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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

In re: AVALANCHE BIOTECHNOLOGIES SECURITIES LITIGATION	Master File No. 15-cv-03185-JD CLASS ACTION
This Document Relates To: All Actions	**CONSOLIDATED CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**

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TABLE OF DEFINED TERMS AND ABBREVIATIONS

Term	Definition
2014 Prospectus	Avalanche's prospectus filed pursuant to its IPO on July 31, 2014
2014 Registration Statement	Avalanche's registration statement no. 333-197133 declared effective by the SEC on July 30, 2014 and 2014 Prospectus incorporated therein.
2015 Prospectus	Avalanche's prospectus filed pursuant to its secondary offering on January 7, 2015
2015 Registration Statement	Avalanche's registration statement no. 333-201032 declared effective by the SEC on January 7, 2015 and 2015 Prospectus incorporated therein.
AAV	Adeno-Associated Virus
AMD	Age-related Macular Degeneration
April 2014 Abstract	Elizabeth P Rakoczy, et al., *One Year Follow-Up Report on the rAAV.sFlt-1 Phase I Gene Therapy Trial for Exudative Age-Related Macular Degeneration*, 55 IOVS 1309 (2014)
ARVO	Association for Research in Vision and Ophthalmology
ASCGT	American Society for Cell and Gene Therapy
AVA-101	Avalanche's lead product candidate, an AAV vector intended to treat Wet AMD
AVA-101 Trial	Avalanche's Phase 1/2a trial of AVA-101 in 40 human subjects with Wet AMD
Avalanche	Avalanche Biotechnologies, Inc.
Bain	Linda C. Bain, former CFO of Avalanche
Barone	Samuel Barone, M.D., CMO of Avalanche
BCVA	Best corrected visual acuity
Blumenkranz	Mark S. Blumenkranz, M.D., Chairman of Avalanche's Board of Directors
CEO	Chief Executive Officer
CFO	Chief Financial Officer
CFP	Color fundus photography

Chalberg	Thomas W. Chalberg, Jr., Ph.D., former CEO of Avalanche
Class Period	July 31, 2014 to June 15, 2015
CMO	Chief Medical Officer
CNV	choroidal neovascularization
Constable	Ian J. Constable AO, researcher at LEI and Chairperson of Avalanche's Clinical Advisory Board
Cowen	Cowen & Co., LLC
CTN Form	Notification of Intent to Conduct a Clinical Trial form
ETDRS	Early Treatment Diabetic Retinophathy Study scale
Exchange Act	Securities Exchange Act of 1934
Exchange Act Defendants	Avalanche, Bain, Blumenkranz, Chalberg, and Schwartz
FA	Fluorescein Angiography
Gasmi	Mehdi Gasmi, Senior Vice President of Pharmaceutical Development
HREC	Human and Research Ethics Committee
Hull	Hans Hull, Avalanche's Senior Vice President of Business Operations
IND	Investigational New Drug application
Individual Exchange Act Defendants	Bain, Blumenkranz, Chalberg, and Schwartz
Individual Securities Act Defendants	Bain, Blumenkranz, Chalberg, McLaughlin, Schwartz, and Wachter
IOP	Intraocular Pressure
IOVS	Investigative Ophthalmology & Visual Science
IPO	Avalanche's Initial Public Offering conducted on or around July 31, 2014
Jefferies	Jefferies, LLC
LEI	Lions Eye Institute
McLaughlin	John P. McLaughlin, director on Avalanche's Board of Directors

Piper Jaffray	Piper Jaffray & Co.
Rakoczy	Elizabeth Rakoczy, MSc, Ph.D., researcher at LEI and Chairperson of Avalanche's Scientific Advisory Board
Schwartz	Steven W. Schwartz, M.D., director on Avalanche's Board of Directors
SD-OCT	Spectral Domain Optical Coherence Tomography
SEC	Securities and Exchange Commission
Securities Act	Securities Act of 1933
Securities Act Defendants	Avalanche, Bain, Blumenkranz, Chalberg, McLaughlin, Schwartz, Wachter, Cowen & Co., Jefferies, Piper Jaffray, and William Blair
TGA	Therapeutic Goods Administration
Trial Protocol	Protocol for Avalanche's Phase 1/2a trial of AVA-101 in 40 human subjects with Wet AMD
Underwriter Defendants	Cowen & Co., Jefferies, Piper Jaffray, and William Blair
VEGF	Vascular endothelial growth factor
Wachter	Paul D. Wachter, director on Avalanche's Board of Directors
William Blair	William Blair & Company, LLC

GLOSSARY

Term	Definition
Adeno-Associated Virus (AAV)	A harmless, small virus that infects most humans and does not instigate an immune response.
Antibody	Proteins in the blood that are recruited by the immune system to identify and neutralize foreign objects like bacteria and viruses.
AVA-101	A vector to deliver and express a function gene to eye cells to promote continuous protein production, a/k/a AAV.sFlt1"
Baseline Data	Data collected at the beginning of a clinical study for all participants.
Best Corrected Visual Acuity (BCVA)	Visual acuity measure after corrective tool or treatment is used.
Biomicroscopy	Standard examination of the eye using a slit-lamp and magnifying lens.
Choroid	The vascular layer of the eye, containing connective tissue. It makes up part of the uvea layer of the eye which sits underneath the retina.
Choroidal Neovascularization (CNV)	The creation of new blood vessels in the choroid layer of the eye which is one layer beneath the retina.
Color Fundus Photography (CFP)	Color photographs taken of the retina.
Early Treatment Diabetic Retinopathy Study Scale (ETDRS)	A standard eye chart used to test visual acuity characterized by 5 roman letters per row with rows descending in size.
Fluorescein Angiography (FA)	A medical procedure where fluorescent dye is injected into the blood stream and then the dye highlights the blood vessels in the back of the eye so they can be photographed.
Fovea	The center of the macula that forms a small pit and contains the largest concentration of cone cells in the eye making it responsible for central, high-resolution vision.
Foveal Thickness	Retinal thickness

Human and Research Ethics Committee (HREC)	Committees affiliated with organizations that conduct research on humans. The TGA requires all clinical trials of unregistered therapeutic goods to be reviewed and monitored by an HREC.
Indirect Ophthalmoscopy	Standard examination of the interior of the eye using a headband with a light attached and small hand-held lens.
Intraocular Pressure (IOP)	Fluid pressure inside the eye caused by an excess of aqueous fluid.
Intravitreal Injection	Injection to the jelly-like fluid in the center of the eye.
Investigational New Drug Application (IND)	A request for Food and Drug Administration authorization to administer a drug under clinical development to humans.
Macula	An oval-shaped pigmented area near the center of the retina which is responsible for central vision.
Ocular Inflammation	Swelling of the uvea layer of the eye that sits underneath the retina.
Open-Label Trial	The type of clinical trial where both the investigators and the subjects know whether placebo or treatment is being administered.
Opthalmic Safety	Safety relating to the eye.
Primary Endpoint	Measures the outcome that will answer the primary (or most important) question being asked by a trial, such as whether a new treatment is better at preventing disease-related death than the standard therapy.
rAAV.sFlt-1	AVA-101
Ranibizumab	Current treatment of wet-AMD marketed by Genetech, Inc. under the name "Lucentis."
Rescue Injection	Additional subretinal injection of ranibizumab
Retina	The light-sensitive layer at the back of the eye that covers about 65 percent of the interior surface of the eye.
Secondary Endpoint	Measures relevant questions being asked by a clinical trial in addition to the primary endpoint.

sFLT-1	The naturally-occurring anti-VEGF protein found in AVA-101.
Spectral Domain Optical Coherence Tomography (SD-OCT)	A non-contact medical imaging technology where reflected light is used to produce detailed cross-sectional and 3D images of the eye.
Statistical Significance	The likelihood that a relationship or result is caused by something other than mere random chance. Statistical hypothesis testing is employed using a "p-value" representing the probability that random chance could explain the result. A p-value of less than 5% is usually considered statistically significant.
Subretinal Injection	Injection into the retinal layer of the eye.
Therapeutic Goods Administration (TGA)	The regulatory body for therapeutic goods (including medicines, medical devices, gene technology, and blood products) in Australia.
Trial Protocol	A document that describes how a clinical trial will be conducted (the objective(s), design, methodology, statistical considerations and organization of a clinical trial,) and ensures the safety of the trial subjects and integrity of the data collected.
Vascular Endothelial Growth Factor (VEGF)	A signal protein produced by cells to stimulate the creation of blood cells to restore the oxygen supply to tissues when blood flow is inadequate.
Viral Vector	Virus cell that has had the disease-causing genes removed and is then inserted into the body to transfer desired genes to targeted cells by infecting those cells.
Visual Acuity	The clearness or sharpness of vision measured at a distance of 20 feet.
Vitreous Cavity	The center cavity of the eye behind the lens that is filled with vitreous gel.
Wet Age-Related Macular Degeneration (Wet AMD)	Disease of the eye whereby blood vessels form in the macula causing bleeding, leakage, and scarring in the retina and distorting central vision.

The allegations in this Consolidated Class Action Complaint are based on the personal knowledge of Lead Plaintiff Arpan Bachhawat and Plaintiff Srikanth Koneru ("**Plaintiffs**") as to Plaintiffs' own acts, and are based upon information and belief as to all other matters alleged herein. Plaintiffs' information and belief is based upon the investigation by Plaintiffs' counsel into the facts and circumstances alleged herein, including, (i) review and analysis of those public filings Avalanche Biotechnologies, Inc. ("**Avalanche**" and the "**Company**") made with the United States Securities and Exchange Commission ("**SEC**") referenced herein; (ii) review and analysis of those press releases, analyst reports, public statements, news articles and other publications referenced herein disseminated by or concerning Avalanche and the other defendants named herein (together with Avalanche, the "**Defendants**"); (iii) review and analysis of those Company conference calls, press conferences, and related statements and materials referenced herein; and (iv) review and analysis of those other documents referenced herein. Many additional facts supporting the allegations are known only to Defendants and/or are within their exclusive custody or control and/or in the custody and control of the U.S. Food and Drug Administration ("**FDA**") or Australian Therapeutic Goods Administration ("**TGA**"). Plaintiffs believe that additional evidentiary support for their allegations will emerge after a reasonable opportunity to conduct discovery.

NATURE OF THE ACTION

1. Plaintiffs bring this federal class action on behalf of purchasers of publicly traded Avalanche common stock who (1) purchased Avalanche common stock between July 31, 2014 and June 15, 2015, inclusive (the "**Class Period**"), and were damaged thereby, seeking to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "**Exchange Act**"), and Rule 10b-5 promulgated thereunder, and/or (2) purchased Avalanche common stock pursuant or traceable to Avalanche's IPO, defined herein, and were damaged thereby, seeking to pursue remedies under Sections 11 and 15 of the Securities Act of 1933 ("**Securities Act**").

2. Avalanche is a clinical-stage biopharmaceutical company developing novel gene therapies to treat ocular diseases. Avalanche's lead product during the Class Period was AVA-101, a novel gene therapy for wet Age-Related Macular Degeneration ("**Wet AMD**"), the leading cause

of blindness in the developed world. The current treatment for Wet AMD consists of intravitreal injections into the eye every four to eight weeks to maintain stable vision. Patients find this regimen uncomfortable and burdensome, leading many to abandon treatment. AVA-101, on the other hand, was designed to require only a single subretinal injection to maintain ongoing, stable vision, without the need for frequent intravitreal injections like the current therapy.

3. AVA-101 was originally developed by Professor Elizabeth Rakoczy ("**Rakoczy**") at the Lions Eye Institute ("**LEI**"), a research organization based in Perth, Australia; in 2010, Avalanche entered into a license agreement to develop the drug with the help of LEI. Avalanche founder and Chief Executive Officer ("**CEO**") Thomas W. Chalberg, Jr., Ph.D. ("**Chalberg**") and Avalanche director and esteemed ophthalmologist Steven W. Schwartz, M.D. ("**Schwartz**") helped design and approve the AVA-101 Trial (defined below), the first trial of AVA-101 in human subjects.

4. The AVA-101 Trial began in January 2012 and was originally designed to enroll 24 subjects. By March 2014, the Trial Protocol was updated to enroll 40 patients. The primary endpoint was "ophthalmic safety," or eye safety, which was determined by reviewing abnormal laboratory data and conducting an ocular examination to measure (a) ocular inflammation; (b) intraocular pressure; (c) visual acuity; and (d) retinal bleeding. Ophthalmic safety was assessed by using biomicroscopy, indirect ophthalmoscopy, Spectral Domain Optical Coherence Tomography ("**SD OCT**"), Color Fundus (retinal) Photography ("**CFP**"), and Fluorescein Angiography ("**FA**"). The secondary endpoint of efficacy was to determine the existence of stable vision without the need for rescue injections as measured by (a) best-corrected visual acuity ("**BCVA**"); (b) Choroidal neovascularization ("**CNV**") lesion (a/k/a fluid leakage); and (c) foveal thickness (a/k/a retinal thickness). A closer look at these endpoints reveals that they are in fact measured by many, if not all, of the same methods, and thus, a review of the so-called safety data would necessarily involve a review of the data that is likewise indicative of efficacy.

5. As Avalanche and the LEI began reviewing the positive safety/efficacy data for the first patients enrolled in the AVA-101 Trial, Avalanche decided to use the data to engage in a

fraudulent scheme to take the Company public and profit handsomely. In the months leading up to the July 2014 IPO (defined below), Avalanche and LEI began conditioning the market by boasting about the first year results for the original 8 patients enrolled in the AVA-101 Trial which they coined "Phase 1"—never mind that this data was collected a year prior and not announced at that time. In April 2014 and again in May, LEI, Chalberg, Schwartz, and founder and chairman of Avalanche's Board of Directors, Mark S. Blumenkranz, M.D. ("**Blumenkranz**"), among others, published an abstract showing that the first 8 patients in Phase 1 of the AVA-101 Trial (the remaining 32 patients enrolled in the trial were called "Phase 2a") experienced a thinning of the retina, increase in visual acuity, and decrease in the need for rescue injections as compared to the control group who had received the current standard of care. In addition to the abstracts, LEI touted the positive Phase 1 results to the media. For example, on May 19, 2014, LEI published a media release announcing that AVA-101 "could spell the end of invasive monthly injections into the eye[.]"

6. With the market excited over the preliminary results from the AVA-101 Trial and eagerly anticipating announcement of the results from the remaining 32 patients in the second half of 2015, Defendants launched an IPO, issuing more than 6 million shares to the public. Avalanche's debut was met with an outstanding reception. On July 31, 2014, the date of the IPO, the Company's stock price closed $10 higher than the $17 IPO price and when the analysts joined the party in August 2014, they all set a price target at or above $40. What Avalanche had failed to disclose to the market when it was reaping a handsome profit and padding the bank accounts of its executives is that in June 2014—a month prior to the IPO—when it received "interim drug safety surveillance data" from the AVA-101 Trial, Avalanche became aware that the drug was not having the desired effect. Indeed, because the safety data and the efficacy data were measured by the same methods, the safety data necessarily also revealed that the drug was causing patients' retinas to thicken, was not causing a sufficient improvement in patients' visual acuity to justify the risk of

adverse safety events, and was leading AVA-101-treated patients to require multiple rescue injections in order to maintain stable vision.[1]

7. For the remainder of 2014, Avalanche continued business as usual. Through presentations at numerous industry and financial conferences, Avalanche continued to expound upon the positive results from Phase 1 of the AVA-101 Trial, pushing Avalanche's stock price to a high of $55.89 by the end of 2014. Based on this record stock price, at the end of 2014, Avalanche decided to conduct yet another public offering of Avalanche common stock. Thus, from a secondary offering launched on January 7, 2015 of approximately 2.5 million shares of common stock at $59 per share, Avalanche collected an additional $130.5 million from the investing public.

8. Meanwhile, armed with the negative efficacy-related data indicating that AVA-101 was not having the desired effect, Avalanche insiders, including the CEO, CFO, and Chairman of the Board, among others, began selling off stock in massive numbers. Taking advantage of the one exception to the IPO lock-up period, insiders sold a total of 290,000 shares of common stock for total proceeds of $16,083,400 in the 2015 Offering, which constituted more than 10% of the total shares sold in the offering. Then, in the two months leading up to the scheduled announcement of the topline results from Phase 2a of the AVA-101 Trial, Avalanche insiders sold an additional 350,000 shares of common stock for total proceeds of $12,908,310.

9. The Avalanche insiders abandoned ship just in time. On June 15, 2015, Avalanche released the top-line results from Phase 2a of the AVA-101 Trial. The results announced showed very clearly that AVA-101 did not work as planned: (a) the retinas of patients treated with AVA-101 thickened whereas the retinas of patients in the control group thinned; (b) patients treated with AVA-101 required between 1 and 6 rescue injections to maintain stable vision whereas patients in the control group needed between 3 and 5 rescue injections; and (c) the vision of patients treated with AVA-101 only improved two letters on the eye chart. Despite reporting blatantly bad results, Chalberg and Samuel Barone ("**Barone**"), Avalanche's Chief Medical Officer, made every effort to

[1] Unless otherwise noted, all emphases are added and all citation and quotations are omitted.

cover their tracks and spin the data in Avalanche's favor by reporting that "the key takeaway is that this was a positive Phase 2a study that met its primary objective which was to further establish the safety of AVA-101 in Wet AMD patients and also help inform future studies going forward." The market was not fooled. On June 16, 2015, shares of Avalanche common stock dropped $21.83, or more than 56%, to close at $17.05 per share. Five weeks later, on July 23, 2015, Avalanche announced that Chalberg would resign as CEO and president and as a member of the Board of Directors effective that day.

10. In fact, these results were so bad that in addition to causing the stock price to lose more than half of its value and the CEO to resign, in August 2015 Avalanche announced that it would be abandoning its trial program for AVA-101 altogether and would instead conduct additional testing to determine the "best gene therapy product candidate for wet AMD to advance back into the clinic." This news again greatly disappointed investors and the stock dropped $3.82, or more than 27%, to close on August 14, 2015 at $10.01 per share.

11. The true facts, which were known and/or recklessly disregarded by defendants but concealed from the investing public during the Class Period, were that beginning in at least June 2014, defendants knew and/or recklessly disregarded and failed to disclose that:

a) patients in Phase 2a of the AVA-101 Trial were experiencing significant thickening of the retina, evidencing that AVA-101 was not effective in treating Wet AMD;

b) patients in Phase 2a of the AVA-101 Trial were requiring multiple rescue injections, evidencing that AVA-101 was not effective in treating Wet AMD;

c) patients in Phase 2a of the AVA-101 Trial were not experiencing significant improvements in visual acuity scores required to justify the increased risk of adverse safety events, evidencing that AVA-101 was not effective in treating Wet AMD; and

d) As a result, Avalanche's business and financial prospects concerning AVA-101 were not what the speakers had led the market to believe they were.

12. As a result of defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common stock when the true facts came to light, Plaintiffs and other Class Members have suffered significant losses and damages.

JURISDICTION AND VENUE

13. This action arises under and pursuant to Sections 11 and 15 of the Securities Act (15 U.S.C. §§ 77k and 77o), and Sections 10(b) and 20(a) of the Exchange Act, (15 U.S.C. §§ 78j(b) & 78t(a)), and SEC Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

14. This Court has jurisdiction over the action pursuant to 28 U.S.C. § 1331, Section 22 of the Securities Act (15 U.S.C. § 77v), and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

15. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa). Avalanche maintains its principal place of business in this District. Certain of the acts and conduct complained of herein, including dissemination of materially false and misleading information to the investing public, occurred in this District.

16. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

NATURE OF THE CLAIMS

17. Plaintiffs assert two different sets of claims in this Complaint. Counts One and Two assert fraud claims under Sections 10(b) and 20(a) of the Exchange Act against Avalanche; Chalberg; Linda C. Bain ("**Bain**"); Blumenkranz; and Schwartz. Counts Three and Four assert strict-liability claims under Sections 11 and 15 of the Securities Act against Avalanche; Chalberg; Bain; Blumenkranz; Schwartz; John P. McLaughlin ("**McLaughlin**"); Paul D. Wachter ("**Wachter**"); Jefferies LLC ("**Jefferies**"); Cowen & Co., LLC ("**Cowen**"); Piper Jaffray & Co. ("**Piper Jaffray**"); and William Blair & Co. ("**William Blair**") Plaintiffs expressly disclaim any allegations of fraud in the non-fraud claims brought under the Securities Act.

THE EXCHANGE ACT CLAIMS

18. These claims brought under the Exchange Act are asserted against Avalanche and certain of its officers and directors, who, during the Class Period, made materially false or misleading statements or omissions in press releases, presentations, analyst reports, and filings with the SEC, *inter alia*; employed devices, schemes, and artifices to defraud; and engaged in acts, practices, and a course of conduct that operated as a fraud or deceit upon Plaintiffs and other members of the Class.

I. THE EXCHANGE ACT PARTIES

A. The Exchange Act Plaintiffs

19. Lead Plaintiff Arpan Bachhawat, as set forth in his shareholder certification (ECF No. 26-3), purchased Avalanche common stock at artificially inflated prices during the Class Period and was damaged thereby.

20. Plaintiff Srikanth Koneru purchased 71 shares of Avalanche common stock at $25.81 per share on July 31, 2014 and was damaged thereby. Plaintiff still holds all of his shares as of the date of the filing of this Complaint.

B. The Exchange Act Defendants

21. Defendant Avalanche is a Delaware corporation with its principal executive offices located at 1035 O'Brien Drive, Suite A, Menlo Park, California 94025. Avalanche is a biopharmaceutical company that uses its proprietary Ocular BioFactory™ platform to discover and develop novel treatments for ophthalmic diseases. During the Class Period, the Company's stock was traded on the NASDAQ Global Select Market ("**NASDAQ**") under the symbol "AAVL."

22. Defendant Chalberg co-founded Avalanche, and, until his resignation on July 23, 2015, was the CEO, president, and a member of the Board of Directors of Avalanche. Because of his positions with the Company, Chalberg had access to all the Company's study protocols, patient data, updates, outcomes, and results. Chalberg directly participated in and controlled the management of the Company, including, without limitation, the publication of statements by and on

behalf of Avalanche concerning AVA-101 in the Company's press releases, SEC filings, and other public statements. Chalberg was motivated by the financial implications of the IPO and the 2015 Offering and personally sold at least 135,000 shares of Avalanche common stock during the Class Period, receiving over $6,415,145 in proceeds.

23. Defendant Bain was at all relevant times the Chief Financial Officer ("**CFO**") of Avalanche. Because of her position with the Company, Bain had access to all the Company's study protocols, patient data, updates, outcomes, and results. Bain directly participated in and controlled the management of the Company, including, without limitation, the publication of statements by and on behalf of Avalanche concerning AVA-101 in the Company's press releases, SEC filings, and other public statements. Bain resigned from the Company on October 19, 2015. Bain was motivated by the financial implications of the IPO and the 2015 Offering and personally sold at least 7,000 shares of Avalanche common stock during the Class Period, receiving over $253,659 in proceeds.

24. Defendant Blumenkranz co-founded Avalanche and, at all relevant times, was the Chairman of the Board of Directors of Avalanche. Because of his position with the Company, Blumenkranz had access to all the Company's study protocols, patient data, updates, outcomes, and results. Blumenkranz directly participated in and controlled the management of the Company, including, without limitation, the publication of statements by and on behalf of Avalanche concerning AVA-101 in the Company's press releases, SEC filings, and other public statements. Blumenkranz was motivated by the financial implications of the IPO and the 2015 Offering and personally sold at least 231,000 shares of Avalanche common stock during the Class Period, receiving over $10,417,890 in proceeds.

25. Defendant Schwartz co-founded Avalanche and, at all relevant times, was a member of Avalanche's Board of Directors. Because of his position with the Company, Schwartz had access to all the Company's study protocols, updates, outcomes, and results. Schwartz directly participated in and controlled the management of the Company, including, without limitation, the publication of statements by and on behalf of Avalanche concerning AVA-101 in the Company's

press releases, SEC filings, and other public statements. Schwartz was motivated by the financial implications of the IPO and the 2015 Offering and personally sold at least 193,348 shares of Avalanche common stock during the Class Period, receiving over $9,000,000 in proceeds.

26. Defendants Chalberg, Bain, Blumenkranz, and Schwartz are collectively referred to hereinafter as the "**Individual Exchange Act Defendants**" and together with Avalanche they are referred to herein as the "**Exchange Act Defendants**."

27. The Individual Exchange Act Defendants, because of their positions with the Company, possessed the authority to control, correct, and/or update the contents of Avalanche's public disclosures to the market. Each of the Individual Exchange Act Defendants had the duty to exercise due care and diligence and the duty of full and candid disclosure of all material facts relating to the Company's financial results and operations. The Individual Exchange Act Defendants further had the duty to correct and/or update any previously issued statements that were untrue or became materially misleading or untrue, so that the market price of the Company's publicly traded common stock would be based upon truthful, complete, and accurate information. To discharge their duties, the Individual Exchange Act Defendants were required to exercise reasonable and prudent supervision over the dissemination of information concerning the Company's financial results and operations. By virtue of such duties, these officers and directors were required, *inter alia*, to:

a) conduct and supervise the business of Avalanche in accordance with federal laws;

b) supervise the preparation of Avalanche's SEC filings and approve any reports concerning Avalanche's financial reporting and results; and

c) ensure that Avalanche established and followed adequate internal controls.

28. As officers, directors, and/or controlling persons of a publicly-held company which is registered with the SEC under the federal securities laws and the securities of which were traded on the NASDAQ GM and governed by the provisions of the federal securities laws, the Individual Exchange Act Defendants each had a duty to (1) promptly disseminate complete, accurate and truthful information with respect to the Company's financial statements and operations; (2) correct

any previously issued statements that were materially misleading or untrue so that the market could accurately price the Company's publicly traded securities based upon truthful, accurate, and complete information; and (3) update any previously-issued statements that became materially misleading or untrue so that the market could accurately price the Company's publicly traded securities based upon truthful, accurate, and complete information.

29. The Individual Exchange Act Defendants are each primarily liable for the misrepresentations and misleading statements alleged herein and are also liable as controlling persons of Avalanche. The scheme deceived the investing public regarding Avalanche's AVA-101 Trial, which caused Plaintiffs and other members of the Class to purchase Avalanche common stock at artificially inflated prices during the Class Period and suffer damages as a result.

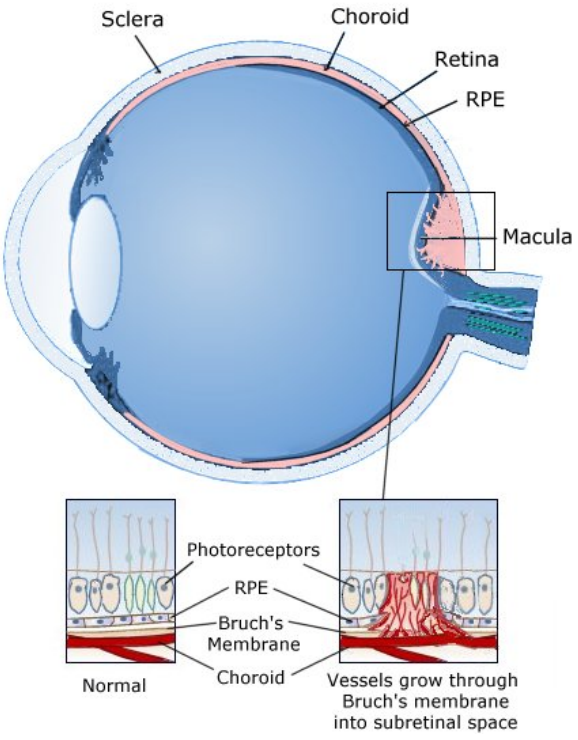
II. BACKGROUND OF THE EXCHANGE ACT CLAIMS

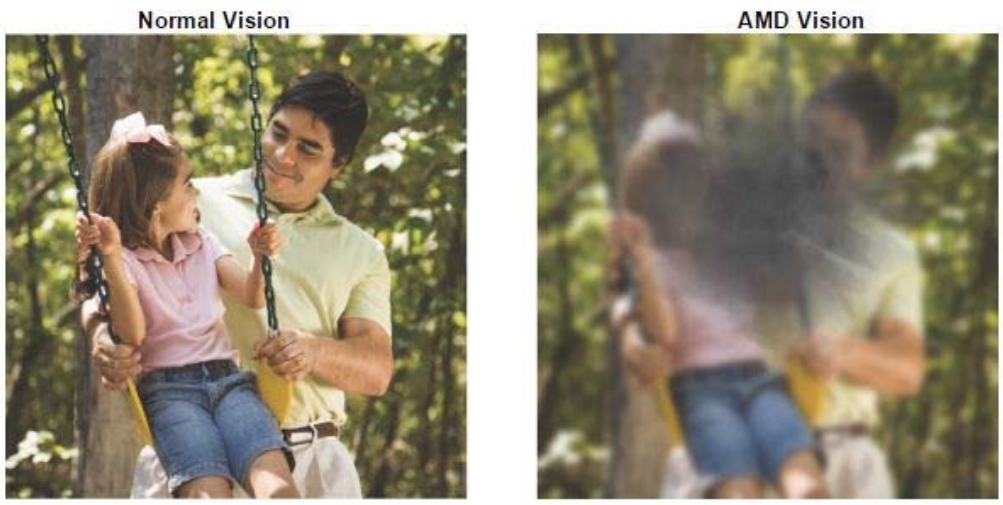
A. Background of the Company, Wet AMD, and AVA-101

30. Avalanche is a biopharmaceutical company focused on the development and commercialization of a gene therapy platform, dubbed its Ocular BioFactory™ platform, which is designed to treat ophthalmic diseases. *See* Avalanche Biotechnologies, Inc., *The Ocular BioFactory*™, http://www.avalanchebiotech.com/the-ocular-biofactory.php (last visited Jan. 29, 2016). Avalanche's Ocular BioFactory™ platform consists of treatments that use the adeno-associated virus ("**AAV**") as a vector to deliver and express a functional gene to the cells of the eye to promote continuous production of a certain protein. *See id.*

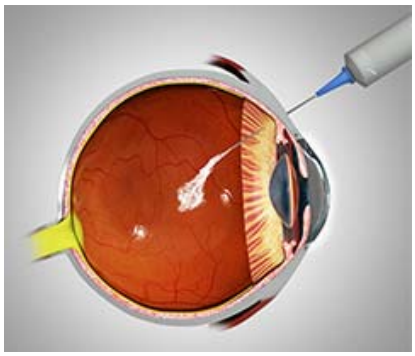
31. Avalanche's lead AAV vector is AVA-101, a/k/a rAAV.sFlt-1, which is being developed to treat Wet AMD. *See* Ex. B, Avalanche Biotechnologies Inc., Registration Statement (Form S-1), 1 (July 30, 2014) (the "**2014 Registration Statement**"). AMD is a progressive disease affecting the cells in the macula, which is an oval-shaped pigmented area that forms the center of the retina and is the region of the eye responsible for central vision. *See* Avalanche Biotechnologies, Inc., About Age-Related Macular Degeneration, http://www.avalanchebiotech.com/about-amd.php (last visited Jan. 18, 2016).

32. Wet AMD is an advanced form of AMD whereby patients suffer from debilitating vision loss and loss of the ability to perform daily activities. *See* Salveen Richter, SunTrust Robinson Humphrey, *An Eye To a Cure, Initiating with a Buy and $60 PT*, 14 (2015). Wet AMD occurs when the membrane underlying the retina thickens, then breaks. *See* The Macular Degeneration Partnership, Wet AMD, https://www.amd.org/what-is-macular-degeneration/wet-amd/ (last visited Jan. 29, 2016). The oxygen supply to the macula is disrupted and the body responds by growing new, abnormal blood vessels, which is known as choroidal neovascularization ("**CNV**"). *See id.*; *see also* American Macular Degeneration Foundation, *Wet Macular Degeneration (AMD)*, https://www.macular.org/wet-amd (last visited Jan. 29, 2016). These new blood vessels are very fragile and often leak and bleed, which results in excess fluid in the retina causing swelling, or thickness of the retina. *See* The Macular Degeneration Partnership, *Wet AMD*, https://www.amd.org/what-is-macular-degeneration/wet-amd/ (last visited Jan. 29, 2016). The leakage from these blood vessels also damages photo receptors, which results in rapid vision loss. *See id.* A diagram of this process and a demonstration of the type of vision loss experienced are set forth below:



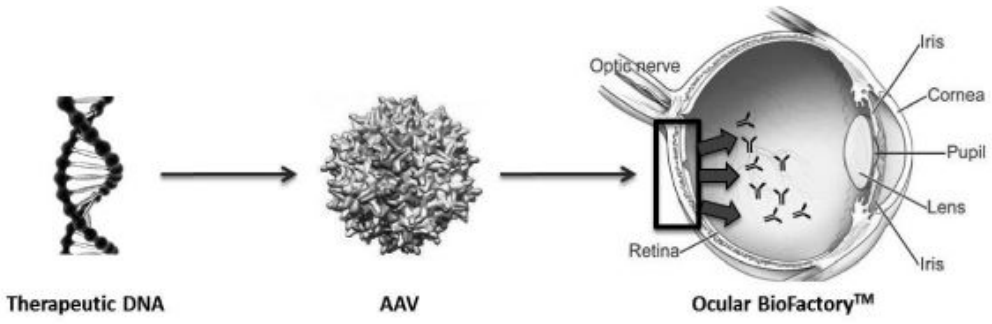


33. Vascular endothelial growth factor ("**VEGF**") is a protein known to play a central role in the growth of the new blood vessels in the retina. *See* Avalanche Biotechnologies, Inc., Current Treatments, http://www.avalanchebiotech.com/current-treatments.php (last visited Jan. 18, 2016). A number of FDA-approved therapies have been developed to block the effects of VEGF by binding to and sequestering the protein, causing the new blood vessels to shrink. *See id.* The most common FDA-approved anti-VEGF treatments are (1) Lucentis® (ranibizumab), marketed by Genentech, Inc. and Novartis AG, which is an antibody fragment that binds to and inhibits VEGF proteins in the eye; (2) EYLEA®, marketed by Regeneron Pharmaceuticals, Inc., which is a recombinant fusion protein containing portions of the human VEGF receptor that binds to soluble VEGF; and (3) Avastin®, marketed by Genentech, Inc., which is an antibody that binds to VEGF. *See id.* These treatments are administered through intravitreal injections, which are simply injections into the center of the eye, depicted as follows:

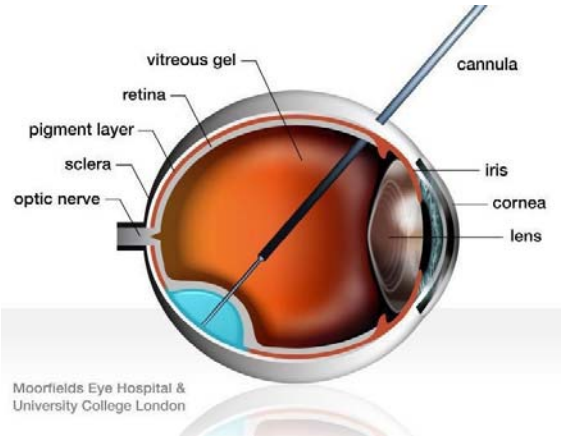


34. Because these biologic agents decay over time, causing "peaks" and "troughs" of VEGF inhibition, they require injections every 4 to 8 weeks to maintain stable vision. *See* Salveen Richter, SunTrust Robinson Humphrey, *An Eye To a Cure, Initiating with a Buy and $60 PT*, 14 (2015). While these therapies have proven to be effective in treating the symptoms of Wet AMD, the frequency and discomfort of administration is burdensome for patients, leading many to terminate treatment or not comply with the prescribed regimen, resulting in vision loss. *See id.*

35. In contrast to the current standards of care which are laboratory-manufactured antibodies, AVA-101 purports to be a novel gene therapy. This gene therapy utilizes a viral vector to carry the desired genetic information—nucleic acids that encode a protein of interest—to target cells and cause them to utilize the cell's machinery to express the protein of interest. *See* Aaron Shapiro, *Gene Therapy for Retinal Diseases*, Retina Today, April 2015, at 24. The goal of gene therapy is to provide a sustained therapeutic benefit via continual expression of the protein of interest. *See id.* AVA-101 is comprised of the AAV2 vector, which contains a gene encoding sFLT-1, a naturally occurring anti-VEGF protein. *See* 2014 Registration Statement at 81. Avalanche hypothesized that when administered in the eye and expressed by the host retinal cells, the sFLT-1 protein would inhibit the formation of new blood vessels and blocks VEGF activity. *See id.* A diagram of how AVA-101 was intended to operate in the eye is included below:

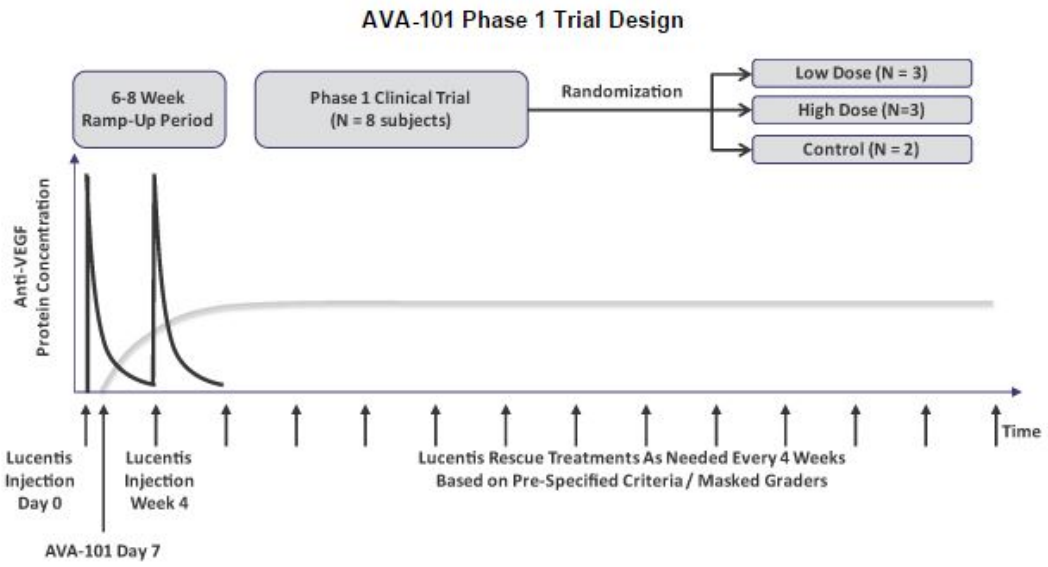


36. Unlike the current FDA-approved therapies, AVA-101 is designed to be administered through a ***single subretinal injection***. *See* 2014 Registration Statement at 81. Subretinal injections are injections through the middle of the eye, directly into the retina in the back of the eye, depicted as follows:



37. The purpose of this type of invasive injection is to place the vector in direct contact with the retinal cells to enhance protein expression. *See id.* Subretinal injections are more difficult to administer and more invasive than intravitreal injections, requiring an operating room and anesthesia. *See* Salveen Richter, SunTrust Robinson Humphrey, *An Eye To a Cure, Initiating with a Buy and $60 PT*, 23 (2015). They are also subject to more adverse safety events such as "the development of a retinal hole at the site of entry through the retina, reflux of the therapeutic agent back into the vitreous cavity, potentially decreasing efficacy or scar formation from proliferation of cells on the retinal surface, and prolonged retinal detachment." Biren Amin, Jefferies, *Initiate at Buy: AAVL Gene Therapy Has Disruptive Potential in Wet AMD*, 16-17 (Aug. 25, 2014). Therefore, as analysts noted during the Class Period, "there does need to be a compelling clinical benefit for a subretinal delivery product in terms of either a very meaningful (50% or more) average reduction in injection frequency or a relevant (>1 line vision) average improvement in visual acuity." Joshua E. Schimmer, Piper Jaffray, *AAVL Earnings and Model Update*, 1 (Mar. 5, 2015).

38. If effective, AVA-101 could result in sustained production of a natural inhibitor of VEGF, and therefore stabilize cellular levels of VEGF. Thus, a one-time subretinal injection of AVA-101 is designed to introduce a lasting source of VEGF inhibition in the eye and enable constant prevention of new blood vessel formation, eliminating the need for intravitreal injections every 4 to 8 weeks. *See* Salveen Richter, SunTrust Robinson Humphrey, *An Eye To a Cure, Initiating with a Buy and $60 PT*, 14 (2015). A graphic of this difference is as follows:



B. The Phase 1/2a AVA-101 Trial Design

39. Research and development of the science behind AVA-101 began more than 20 years ago, spearheaded by Rakoczy at LEI, an ophthalmic research organization based in Perth, Australia. *See* Lions Eye Institute, Annual Report, 34 (2013). Over the years, close to 100 scientists, ophthalmologists, veterinarians, virologists, and PhD students participated in the project. *See id.* From 2002 to 2007 a grant from the National Health and Medical Research Council enabled the research team to take the basic research project to the clinical trial phase. *See id.*

40. LEI began collaborating with Avalanche on its AVA-101 research in approximately 2008. *See* Lions Eye Institute, Annual Report, 10 (2014). In March 2010, Avalanche entered into a research collaboration agreement with LEI whereby Avalanche licensed certain intellectual property rights in LEI's ophthalmology platform, including the rights to develop AVA-101. *See* Avalanche Biotechnologies, Inc., Registration Statement (Form S-1), F-22 (2015) ("**2015 Registration Statement**"). Under the terms of the agreement, LEI agreed to conduct certain clinical research studies and Avalanche committed to funding the research and issued LEI warrants to purchase 400,000 shares of Avalanche common stock. *See id.* In October 2010, Rakoczy and Professor Ian Constable ("**Constable**")—the individuals responsible for developing AVA-101 at LEI—were then appointed as the Chairs of Avalanche's Scientific Advisory Board and Clinical

Advisory Board, respectively. *See* Avalanche Biotechnologies, Inc., *Scientific Advisory Board*, http://www.avalanchebiotech.com/scientific-advisory-board.php (last visited Jan. 29, 2016); Avalanche Biotechnologies, Inc., *Clinical Advisory Board*, http://www.avalanchebiotech.com/clinical-advisory-board.php (last visited Jan. 29, 2016).

41. Shortly thereafter, Chalberg and Schwartz collaborated with Rakoczy and Constable to create the study design and seek regulatory approval of a multi-phase trial to test AVA-101 in human patients. *See* Elizabeth P Rakoczy, et al., *Gene therapy with recombinant adeno-associated vectors for neovascular age-related macular degeneration: 1 year follow-up of a phase 1 randomised clinical trial*, 386 The Lancet 2395, 2402 (2015).

42. Similar to an Investigational New Drug ("**IND**") application in the United States, prior to testing any therapeutic goods in humans in Australia, Australia's TGA requires that the researcher, at the request of the sponsor, submit a Notification of Intent to Conduct a Clinical Trial form ("**CTN Form**") and all material related to the proposed trial, including the trial protocol, to the applicable Human and Research Ethics Committee ("**HREC**"). *See* Department of Health and Ageing, Therapeutic Goods Administration, Human Research Ethics Committees and the Therapeutic Goods Legislation, 7 (2001). The HREC is then responsible for assessing the scientific validity of the trial design and the safety and efficacy of the therapeutic good as well as the ethical acceptability of the trial process. *See id.* Once the sponsor, principal investigator, Chairman of the HREC, and responsible person from the trial site have signed the CTN Form, it is submitted by the sponsor of the trial to the TGA along with the appropriate notification fee. *See id.*

43. After the CTN for the trial was signed and submitted by Avalanche and LEI, along with the trial design and protocol, to the TGA, on December 14, 2011 Avalanche filed with www.clinicaltrials.gov[2] the protocol ("**Trial Protocol**") for its trial entitled "A Phase I/II Controlled Dose-escalating Trial to Establish the Baseline Safety and Efficacy of a Single Subretinal Injection of rAAV.sFlt-1 Into Eyes of Patients With Exudative Age-related Macular Degeneration (AMD)"

[2] clinicaltrials.gov is a website established by the National Institutes of Health.

(the "**AVA-101 Trial**"), identifier number NCT01494805. *See* Ex. C, Clinicaltrials.gov, *Safety and Efficacy Study of rAAV.sFlt-1 in Patients With Exudative Age-Related Macular Degeneration (AMD)*, https://www.clinicaltrials.gov/ct2/show/NCT01494805?term=avalanche&rank=3 (last visited Jan. 25, 2016).

44. The AVA-101 Trial was arranged to take place in Australia with LEI acting as the trial investigator and Dr. Constable performing the injections on each patient. *See id.* Avalanche and LEI were characterized as sponsors and co-collaborators of the study. *See* Ex. D, Lions Eye Institute, Annual Report, 20 (2012). Despite LEI acting as the principal investigator, both entities considered the AVA-101 Trial to be Avalanche's study. Lions Eye Institute, Annual Report, 9 (2014). Avalanche repeatedly stated that "***[w]e are evaluating AVA-101 in a Phase 1/2a*** trial at LEI in Australia[,]" 2015 Registration Statement at 84, and LEI stated in its 2014 Annual Report that "***Avalanche is conducting clinical trials of a treatment for age-related macular degeneration*** – leveraging ground breaking research conducted over many years by LEI[.]" Lions Eye Institute, Annual Report, 9 (2014).

45. The trial was a single-center, open-label[3] study that was originally designed to consist of 24 patients aged 65 or above who have Wet AMD. *See* Ex. C at 1; Thomas W. Chalberg, CEO, Avalanche Biotechnologies, Inc., AVA-101 Phase 2a Study Results Call, 3 (June 15, 2015) (transcript on file with Bloomberg, Inc.). Patients were to be randomized to receive either a high or low dose of AVA-101 (16 patients) or assigned to the control group (8 patients). *See id.* at 1. Patients in all three groups were eligible to receive rescue therapy with ranibizumab as needed. *See* Ex. C at 3.

46. The AVA-101 Trial was one study broken into two phases (Phase 1 and Phase 2a). *See id.* at 2. The AVA-101 Trial was conducted under a single Trial Protocol which provided for the same endpoints for both phases. *See id.* at 1.

[3] An open-label trial is the type of trial where both the investigators and the subjects know which treatment is being administered.

47. The primary endpoint of the AVA-101 Trial—the "safety endpoint"—was to measure "ophthalmic safety" by ensuring there were no signs of unresolved ophthalmic complications, toxicity or systemic complications as measured by laboratory tests from 1 month post injection. *See id.* at 15. "Ophthalmic safety"[4] was to be determined by reviewing abnormal laboratory data and conducting an ocular examination of (a) ocular inflammation; (b) intraocular pressure; (c) ***visual acuity (BCVA)***; and (d) ***retinal bleeding***. *See id.* at 15. Ophthalmic safety was assessed by using biomicroscopy, indirect ophthalmoscopy, Spectral Domain Optical Coherence Tomography (**SD OCT**), Color Fundus (retinal) Photography (CFP),[5] and Fluorescein Angiography (**FA**). *See* Ex. E, Elizabeth P. Rakoczy, et al., *The First Report on a rAAV.sFlt-1 Phase I/II Trial for Wet Age-Related Macular Degeneration (AMD)* (2012) ("At day 60 none of the patients required rescue treatment. ***There was no evidence of visual acuity loss,*** IOP elevation, retinal detachment, or any intraocular or systemic immune response in any of the patients."); *see also* Ex. F, Elizabeth P Rakoczy, et al., *One Year Follow-Up Report on the rAAV.sFlt-1 Phase I Gene Therapy Trial for Exudative Age-Related Macular Degeneration*, 55 IOVS 1309 (2014) ("***Ophthalmic safety was assessed by*** biomicroscopy, IOP, indirect ophthalmoscopy, ***SD OCT***, CFP and ***FA***.") (the "**April 2014 Abstract**"); Ex. G, Elizabeth P. Rakoczy, et al., *Gene therapy with recombinant adeno-associated vectors for neovascular age-related macular degeneration: 1 year follow-up of a phase 1 randomised clinical trial*, 386 The Lancet 2395, 2402 (2015) ("***Ocular safety was monitored at each monthly visit with BCVA***, intraocular pressure, slit lamp biomicroscopy, indirect ophthalmoscopy, and ***SD-OCT***[.]").

48. The secondary endpoint of the AVA-101 Trial—the "efficacy endpoint"—was to determine the maintenance or improvement of vision without the need for ranibizumab rescue

[4] *See* Avalanche Biotechnologies, Inc., Current Report (Form 8-K) (June 15, 2015) ("Phase 2a clinical study for AVA-101 met its 12-month primary endpoint, based on ophthalmic and systemic safety[.]"); Avalanche Biotechnologies Inc., Quarterly Financial Report (Form 10-Q), 16 (Nov. 9, 2015) ("The primary endpoint of the Phase 2a study was based on ophthalmic and systematic safety[.]").

[5] Color fundus (retinal) photography simply takes a color picture of the back of the eye, including the macula.

injections. This was to be measured by (a) best-corrected visual acuity (BCVA); (b) CNV lesion (a/k/a fluid leakage);[6] and (c) foveal thickness (a/k/a retinal thickness). *See* Ex. C at 15. The endpoint evaluation was scheduled to take place at one month with extended follow up for three years. *See id.* A chart displaying the two sets of endpoints is set forth below:

Primary Endpoint—Safety Measures	**Secondary Endpoint—Efficacy Measures**
visual acuity (BCVA)	visual acuity (BCVA)
Spectral Domain Optical Coherence Tomography (SD OCT)	Spectral Domain Optical Coherence Tomography (SD OCT)
Fluorescein Angiography (FA)	Fluorescein Angiography (FA)
biomicroscopy	rescue injections
indirect ophthalmoscopy	
Color Fundus (retinal) Photography (CFP)	
ocular inflammation	
intraocular pressure (IOP)	
retinal bleeding	

49. During the trial, all subjects were to receive two initial doses of ranibizumab at Day 0 and Week 4 and the subjects in the active arms received AVA-101 on Day 7. *See* 2014 Registration Statement at 83. Beginning with the Week 8 visit, ranibizumab was to be given as rescue therapy on an as-needed basis. *See id.*

50. According to Rakoczy:

> Rescue treatment with ranibizumab was given when active choroidal neovascularization progression was detected, as measured by: (1) loss of

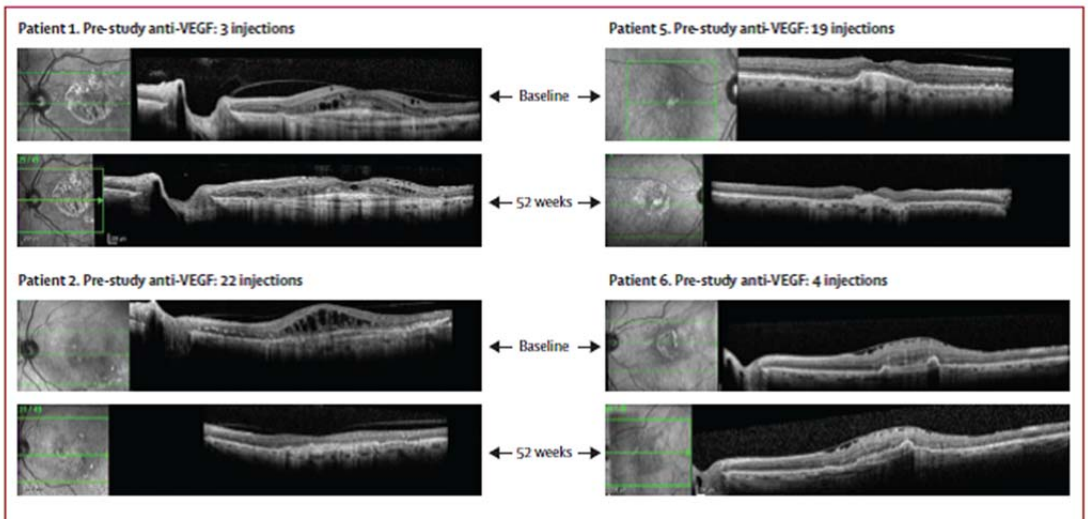
[6] A CNV lesion is the area of the macula where the new blood vessels have begun to form. The presence and size of CNV lesions are determined by looking at the leakage patterns on a fluorescein angiography image (defined below). *See* Amitha Domalpally, et al., *Fluorescein Angiography in Neovascular AMD: An in-depth look at FA's role in detailing lesion composition and characteristics*, Review of Ophthalmology (2008). The statements made by LEI and Avalanche often discuss "FA" or "leakage" and this is all related to determining the presence of CNV lesions.

> ten or more letters on the Early Treatment Diabetic Retinopathy Study (ETDRS) scale from previous visit, or loss of five or more letters from previous visit on ETDRS scale in conjunction with patient perception of functional loss where such loss is attributable to choroidal neovascularisation; (2) any choroidal neovascularization related increased subsensory, intraretinal, or sub-RPE fluid on OCT; or (3) signs of increased choroidal neovascularisation leakage on FA.

Ex. G at 2397. In general terms, this means that rescue injections were based upon pre-specified levels of (1) worsening visual acuity, (2) increases in retinal thickness, and (3) increases in CNV fluid leakage. *See id.* at 2398, 2399, & 2400 (Describing "[b]aseline best corrected visual acuity" by "ETDRS Letters"; discussing retinal thickness results; and describing FA assessments as showing no "recurrence of leakage"). These pre-specified criteria for rescue therapy were chosen to "***assess signals of efficacy***, ***protect patient safety***, and to assess the long term treatment effect" of AVA-101. Ex. G at 2397.

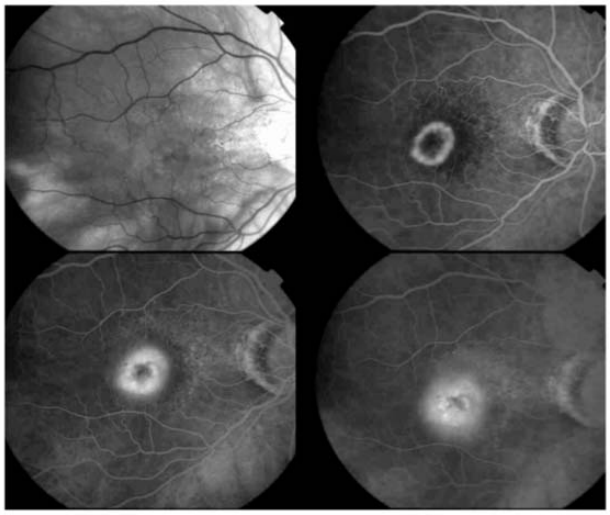
51. Visual acuity is the clearness or sharpness of vision measured at the distance of 20 feet. *See* American Optometric Association, *Visual Acuity: What is 20/20 Vision?*, http://www.aoa.org/patients-and-public/eye-and-vision-problems/glossary-of-eye-and-vision-conditions/visual-acuity?sso=y (last visited Jan. 29, 2016). As explained by Rakoczy, the Early Treatment Diabetic Retinopathy Study ("**ETDRS**") scale, which is a standard eye chart characterized by rows of letters decreasing in size, was used to measure visual acuity in the AVA-101 Trial. *See* Ex. G at 2397. An example of the ETDRS scale is included below:

52. Retinal thickness is increased when there is a buildup of fluid in the retina. The fovea is the largest concentration of cone cells in the eye located in a small pit in the center of the retina. *See* Abstract, Adaptation of the Central Retina for High Acuity Vision: Cones, the Fovea and the Avascular Zone, *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3658155/. In the AVA-101 Trial retinal thickness was measured by Spectral Domain Optical Coherence Tomography ("**SD-OCT**") which is a non-contact medical imaging technology similar to an ultrasound or MRI that takes 3-D cross-sectional images of the retina. Zahid Yaqoob, et al., *Spectral domain optical coherence tomography: a better OCT imaging strategy*, 39 BioTechniques S6 (2005); Press Release, Avalanche Biotechnologies, Inc., *Avalanche Biotechnologies, Inc. Announces Positive Top-Line Phase 2a Results for AVA-101 in Wet Age-Related Macular Degeneration* (June 15, 2015) ("mean change from baseline in retinal thickness as measured by SD-OCT"). SD-OCT images of the retinas of several patients treated in the AVA-101 Trial are included below:



53. Fluid leakage into the retina was detected through a fluorescein angiography ("**FA**") test. *See* Ex. G at 2400; Ophthalmic Photographers' Society, Fluorescein Fundamentals, http://www.opsweb.org/?page=FA (last visited Jan. 29, 2016). FA is performed by injecting a

fluorescent dye into a peripheral vein. *See id.* Then, as the dye courses through and highlights the blood vessels in the eye, a specialized fundus camera or scanning laser ophthalmoscope is used to capture rapid-sequence photographs of the retina to determine the presence of blood vessel leakage. *See id.* Below are FA images of patients with Wet AMD:



54. These three measures—(1) worsening visual acuity, (2) increases in retinal thickness, and (3) increases in CNV fluid leakage—are the mostly commonly accepted measures used to determine whether a drug is inhibiting VEGF and causing an anti-VEGF response in the eye; therefore, they are not only the criteria for giving rescue injections in standard practice—not so coincidentally—they are also the three measures used to determine the secondary endpoint of efficacy. *See* Aetna No. 0701, *Vascular Enothelial Growth Factor Inhibitors for Ocular Indications*, *available at* http://www.aetna.com/cpb/medical/data/700_799/0701.html. Because rescue injections were given to patients in the AVA-101 Trial based upon pre-specified criteria for these three measures, a cursory review of the efficacy data collected would indicate how many rescue injections were given to each patient.

55. The Company attempted to separate the results from the AVA-101 Trial into "safety" and "efficacy" endpoints; however, a closer look makes clear that the methods for measuring these endpoints were in fact the same. "Ophthalmic safety" was to be determined by reviewing abnormal laboratory data and conducting an ocular examination of (a) ocular

inflammation; (b) intraocular pressure; (c) ***visual acuity***; and (d) ***retinal bleeding***. *See* Ex. C at 15. Ophthalmic safety was assessed by using biomicroscopy, indirect ophthalmoscopy, ***SD OCT***, CFP, and ***FA***. *See* ¶47. The secondary endpoint was to determine whether patients treated with AVA-101 required rescue injections by measuring (a) ***visual acuity***; (b) retinal thickness using ***SD-OCT***; and (c) leakage using ***FA***. *See* ¶¶48-54. Accordingly, by reviewing the "safety data" for the AVA-101 Trial, specifically, visual acuity and retinal bleeding and SD-OCT and FA images, the Exchange Act Defendants were also reviewing efficacy data because those same measures were used to determine efficacy, *i.e.* when rescue injections were required. The following chart shows the overlap in the measurements for the primary and secondary endpoints:

Endpoint Measures	Primary—Safety	Secondary—Efficacy
Biomicroscopy	✓	
Indirect Ophthalmoscopy	✓	
Retinal Thickness (SD OCT)	✓	✓
CFP	✓	
CNV Leakage (FA)	✓	✓
Visual Acuity	✓	✓
Ocular Inflammation	✓	
Intraocular Pressure (IOP)	✓	
Retinal Bleeding	✓	
Rescue Injections[7]	✓	✓

C. Progression of Phase 1 of the AVA-101 Trial

56. The AVA-101 Trial began in January 2012, and by April 2012 the first 8 patients had been enrolled. The positive data for the first 8 patients was reported at the meeting of the

[7] As explained in ¶54 a review of visual acuity, SD-OCT, and FA, the three measures used for the efficacy endpoint, which are also measures for the safety endpoint, would indicate the number of rescue injections required.

American Society for Cell and Gene Therapy ("**ASGCT**") held in May 2012. *See* Ex. D, Lions Eye Institute, Annual Report, 20 (2012). The meeting abstract published on May 3, 2012, which was prepared by Chalberg, Schwartz, and Blumenkranz, among others, stated that "***[a]t day 60 none of the patients required rescue treatment***. ***There was no evidence of visual acuity loss***, IOP elevation,[8] retinal detachment, or any intraocular or systemic immune response in any of the patients." Ex. E.

57. On September 11, 2012 Avalanche amended the Trial Protocol for the AVA-101 Trial on www.clinicaltrials.gov to state that the trial would involve 48 patients aged 55 and above. *See* Ex. C at 5. By the end of 2012, 20 patients had been enrolled in the AVA-101 Trial. *See* Ex. D at 20.

58. In June 2013, Avalanche and LEI published an abstract prepared by Chalberg and Blumenkranz, among others, in the Investigative Ophthalmology & Visual Science ("**IOVS**") journal discussing the safety of subretinal injections for ***the first 17 patients*** enrolled in the AVA-101 Trial. *See* Ex. H, Ian Constable, et al., *Anti-VEGF Gene Therapy for Wet AMD: Safety and Tolerability of Subretinal Delivery in a Phase I/II Clinical Trial*, 54 IOVS 4504 (2013). The abstract noted that "[s]ubretinal injection was performed using a commercially available 41g cannula, and documented using a high-definition AJA Ki Pro video system[,]" and "[d]elivery was successfully documented in all 12 subjects." *Id.*

59. The Trial Protocol on www.clinicaltrials.gov, which stated that after the one-month endpoint analysis LEI and Avalanche would conduct an extended three year follow-up of the data, permitted for ongoing data review over the course of three years. *See* Ex. C at 15 (including phrase "up to"). Based upon the abstracts published by LEI and Avalanche, it appears as though LEI and Avalanche were reviewing the data from the AVA-101 Trial on a rolling or ad hoc basis. The 2013 abstract included an analysis of the subretinal injection in ***17 patients*** (not just the first 8) and was announced 18 months after the trial began. *See* Ex. H. Also, the abstract published by LEI and

[8] "**IOP**" is an acronym for intraocular pressure.

Avalanche in the spring of 2014—quoted *infra* (¶¶63-64)—discusses data collected in April 2013, after one year of treatment, and the interim safety data reviewed by Avalanche in June 2014, also discussed *infra* (¶¶74, 80), was collected two and a half years after the trial began.

60. Several statements made by LEI during this time regarding the results from the ongoing trial also suggest that the data was reviewed on a rolling or ad hoc basis. *See* ¶¶68, 69. For example, in its 2013 Annual Report, LEI stated that "***[a]ll patients are doing well*** and we are looking forward to further data analysis in 2014[.]" Lions Eye Institute, Annual Report, 31, 35 (2013). The report also explained that by the end of the year the 38th patient had been enrolled in the AVA-101 Trial. *See id.*

61. On February 25, 2014, Avalanche amended the AVA-101 Trial Protocol on www.clinicaltrials.gov to state that the trial would involve a minimum of 39 and up to 48 subjects. *See* Ex. C at 10. Less than a month later, on March 18, 2014, the Trial Protocol was amended yet again to state that the AVA-101 Trial would involve approximately 40 subjects aged 55 or older. *See id.* at 11.

D. Avalanche's Fraudulent Scheme to Take the Company Public

1. Announcement of the Phase 1 Results

62. In the several months leading up to Avalanche's IPO in July 2014, The Exchange Act Defendants rolled out part one of their scheme to reap millions of dollars by taking the company public. In order to ensure that Avalanche would be offered up at the highest price, LEI and Avalanche began to garner the industry's enthusiasm over Avalanche and its Ocular BioFactory™ platform by announcing and aggressively promoting the positive results from the first 8 patients enrolled in the AVA-101 Trial.

63. For example, in April 2014, Avalanche and LEI published an abstract prepared by Chalberg, Blumenkranz, and Schwartz, among others, in the IOVS journal touting the one-year results from the first phase of the AVA-101 Trial (the April 2014 Abstract). *See* Ex. F. The timing and content of this announcement was suspect for two reasons. First, the results were reported a year after they were collected in April 2013. Second, this was the first time that the first 8 patients

enrolled in the AVA-101 Trial prior to April 2012 were broken out from the full trial and referred to as "Phase 1" and the remaining patients in the trial (ultimately 32) were referred to as "Phase 2a." *See id.*

64. The April 2014 Abstract touted the large gain in visual acuity, decrease in retinal thickness, and decreased need for rescue injections in the treated group:

> ***There was no evidence of loss of visual acuity***, intraocular pressure elevation, retinal detachment, or intraocular or systematic inflammation in any patients in the last study visit. . . .
>
> ***SD OCT demonstrated the decrease or lack of fluid in the retina of all patients. Average center point thickness was 552 + 132 um at baseline and decreased to 352 + 68 um at 1 year***. . . .
>
> ***The average visual acuity was 41.8 EDTRS letters at baseline, which increased to 49.3 letters at one year***. . . .
>
> During the one year follow up period, subjects were allowed retreatment with ranibizumab according to strict, masked re-treatment criteria; ***out of a possible 72 injections, 2 rescue injections were given. Control subjects received 10X as many retreatments during the criteria-driven PRN period***. . . .
>
> These results suggest that subretinal rAAV.sFlt-1 injection is safe, and well tolerated by the elderly study population, and that ***previous or concurrent ranibizumab injections do not interfere with safety***.

See id.

65. A careful read of the April 2014 Abstract, however, shows that the efficacy data and safety data are often conflated as they are really collected through the same data measures.

66. In April 2014, Retina Today published an article quoting Chalberg's presentation of the results at the Angiogenesis, Exudation, and Degeneration 2014 Conference held on February 8, 2014. *See Ocular Gene Therapy Showed Fewer Injections Needed, Increased Visual Gain*, Retina Today (Apr. 2014), *available at* http://retinatoday.com/2014/04/ocular-gene-therapy-showed-fewer-injections-neededincreased-visual-gain. Quoting Chalberg, the article stated: "[o]cular gene therapy might be a long-term viable option for patients with Wet AMD" and repeated much of the positive data from the April 2014 Abstract:

> The control group, which did not receive an injection of AVA-101, required a mean 3 injections of ranibizumab during the 12-month period.
>
> ***The treatment group required a mean 0.3 ranibizumab injections over the same period***. . . .
>
> "Because these patients are coming heavily pretreated, we didn't necessarily expect them to gain additional vision," Dr. Chalberg said. "***But treated patients actually gained between 9 and 12 letters over 12 months***."
>
> Dr. Chalberg reported no drug-related adverse events, retinal tears, or retinal detachments. Procedure-related adverse events were minor and self-resolving.

67. On May 5, 2014, LEI and Avalanche again presented the April 2014 Abstract boasting a positive anti-VEGF response from the newly coined Phase 1 of the AVA-101 Trial at the annual meeting of the Association for Research in Vision and Ophthalmology, Inc. ("**ARVO**").

68. Shortly thereafter, on May 19, 2014, LEI published a media statement entitled "New Gene Therapy Could Bring Relief for Eye Disease Patients" in which LEI expressed its excitement over the interim data from the AVA-101 Trial and declared that the results "could spell the end of invasive monthly injections into the eye[.]" The media statement also disclosed the following:

> Principal clinical investigator Professor Ian Constable and ***the LEI clinical team have recruited 40 patients to the trial***. Professor Constable said the ***gene therapy was proving well tolerated and promising in human trials currently under way***.
>
> Early results on safety and efficacy from the first eight patients in the trial were reported to the Association for Research in Vision and Ophthalmology (ARVO) annual conference in Florida earlier this month by principle scientific investigator Winthrop Professor Elizabeth Rakoczy.
>
> "***To date, the safety profile is excellent – we have found no serious adverse effects in the eye – and so far we have promising data on how it works***," Professor Constable said.

69. LEI also published a Spring Newsletter that contained the same content as the May 19, 2014 media release. *See* Lions Eye Institute, Spring Newsletter, 3 (2014).

70. In the midst of this excitement, in June 2014 Avalanche received the "[i]nterim drug safety surveillance data" from the AVA-101 Trial which suggested that "AVA-101 continues to be well tolerated[.]" 2014 Registration Statement at 2. Despite the fact that since 2012 Avalanche and

LEI had consistently announced positive interim data from the AVA-101 Trial, none of this interim data was disclosed to the public.

71. On July 15, 2014, Ophthalmology Times published an article—reviewed by Rakoczy—discussing the "[p]reliminary encouraging data on long-term gene therapy for exudative age-related macular degeneration" from "the first 8 of 40 patients enrolled" in the AVA-101 Trial. *See* Nancy Groves, *Long-term gene therapy for wet AMD promising: One year follow-up on rAAV.sFt-1 finds no evidence of inflammation, IOP elevation, events, clinical changes*, Ophthalmology Times, July 15, 2014. In regard to the design of the trial, the article quoted Dr. Rakoczy stating, "'[w]e wanted to make sure that during that time they were protected against the harmful effects of neovascularization in the eye' . . . After that, ranibizumab was provided only as rescue therapy." *See id.*

72. In regard to the results, the article reiterated that safety was excellent, that retinal thickness decreased, patients gained visual acuity, and patients required nearly no rescue injections. Specifically, the article stated:

> ***In the phase I trial, a single subretinal injection of rAAV.sFlt1—*** a viral vector used to deliver a gene that expresses a therapeutic protein in the eye***—was safe and well tolerated.***
>
> ***"The safety is excellent, and we have seen longterm benefits for the patients from this approach,"*** said Elizabeth Rakoczy, MSc, PhD . . . "***Patients who receive our treatment do not need any retreatments, or very few, and the growth of new blood vessels in the eye can be controlled without any additional intervention***." . . .
>
> ***Subjects who received the sustained delivery device had an average 6 to 9-letter gain in best-corrected visual acuity versus a 3-letter loss in the control group***. The mean visual acuity at baseline was 42 EDTRS letter compared to 49 letters at one year. In all, 5 of the 6 treated subjects gained vision. . . .
>
> ***The mean center point retinal thickness of rAAV.sFlt1 treated patients decreased by 35% at one year***.
>
> ***Although rescue therapy with ranibizumab was allowed, only 2 of a possible 66 injections were given in the active treatment group***. In the control group, one patient needed 5 injections, while the other received 1.

2. The IPO and the 2015 Offering

73. The second part of the Exchange Act Defendants' scheme was to monetize the positive results from the first 8 patients from the AVA-101 Trial. Indeed, Avalanche took full advantage of the growing excitement over the favorable Phase 1 results of the AVA-101 Trial and on May 30, 2014 launched its Initial Public Offering ("**IPO**") by filing a registration statement with the SEC on Form S-1 (Registration No. 333-197133). Following amendment, on July 30, 2014 the SEC declared the registration statement effective. Avalanche, the Individual Exchange Act Defendants, and the underwriters priced the IPO at $17 per share. On July 31, 2014, the first day of the Class Period, Avalanche and the Individual Exchange Act Defendants filed the final prospectus for the IPO (the "**2014 Prospectus**"), which forms part of the registration statement (the 2014 Prospectus and registration statement are collectively referred to herein as the "**2014 Registration Statement**"), and sold 6,900,000 shares of common stock to the investing public. The IPO was completed on August 5, 2014 and Avalanche raised $106.8 million, after deducting underwriting discounts and commissions and estimated offering expenses. *See* Avalanche Biotechnologies, Inc., Current Report (Form 8-K) (Aug. 5, 2014). The IPO provided for a lock-up period, whereby no directors or executive officers of Avalanche were permitted to sell their shares, for 180 days from the date of the 2014 Prospectus, or until January 17, 2015. *See* 2014 Registration Statement at 44.

74. In the 2014 Registration Statement Avalanche explained that "AVA-101 is currently being studied in a 40 subject Phase 1/2a trial that we are conducting together with LEI" and described the structure and purpose of the AVA-101 Trial, including that the "primary endpoint is safety and secondary endpoints include retinal thickness, visual acuity and the need for rescue injections with anti-VEGF therapy (Lucentis)." 2014 Registration Statement at 78, 86. The 2014 Registration Statement also disclosed that "[i]nterim drug safety surveillance data received in June 2014 from this ongoing study suggests that AVA-101 continues to be well tolerated." 2014 Registration Statement at 2. By failing to disclose what the actual safety data consisted of, the Exchange Act Defendants prevented the market from connecting the dots and realizing that the primary endpoints were actually measuring many of the same responses.

75. Avalanche's debut was met with an outstanding reception by the investment community. On July 31, 2014, the first trading day, Avalanche's stock price closed at $27.99, climbing nearly 40%, even after being priced above expectations. This reaction was primarily due to the data from Phase 1 of the AVA-101 Trial. Cowen & Company initiated coverage on August 25, 2014, attributing its Outperform rating and price target of $45 to the "promising early data that suggests [AVA-101] has the potential to be a functional cure for wet AMD." Phil Nadeau, Cowen & Co., *Initiation: One Stick in the Eye Is Better Than Many*, 1 (2014). William Blair initiated coverage the same day with an Outperform rating and what it considered a "likely conservative" price target of $52 based upon the data collected to date because the valuation included a risk adjustment of a 50% probability that the AVA-101 Trial will be successful. Tim Lugo, William Blair, *Eyeing the Next Disruption in the AMD Market; Initiating Coverage With Outperform Rating and $52 Price Target*, 1 (2014). With a Buy rating and slightly lower price target of $40, Jefferies initiated coverage stating, "AAVL shares hold significant promise based on PI data with AVA-101 observing meaningful VA improvements and durable responses in wAMD patients, which supports a favorable outlook for the PIIa study expected in mid-'15." Biren Amin, Jefferies, *Initiate at Buy: AAVL Gene Therapy Has Disruptive Potential in Wet AMD*, 1 (2014).

76. For the remainder of 2014 Avalanche went out into the market and touted the safety and efficacy of AVA-101 as a treatment for Wet AMD. Indeed, Avalanche presented at least seven different medical and investment conferences over the course of four months. *See* Avalanche Biotechnologies, Inc., *2014 News Releases*, http://investors.avalanchebiotech.com/phoenix.zhtml?c=253634&p=irol-news&nyo=2 (last visited Jan. 29, 2016). The Powerpoint presentation Avalanche made at many of the industry conferences contained broad assertions regarding AVA-101's efficacy including that ***"[o]ne-time, subretinal injection offers 'functional cure' of wet-AMD***" and "***[s]ubjects gained/maintained vision with no or minimal need for additional treatment over one year***." *See* ¶¶109-111 *infra*.

77. The hype generated by Avalanche and the Individual Exchange Act Defendants caused the Company's stock price to skyrocket to a high of $55.89 by the end of 2014. Avalanche

and the Individual Exchange Act Defendants decided to take advantage of this record-high stock price and on December 18, 2014, Avalanche filed with the SEC its registration statement on Form S-1 (Registration No. 333-201388) for a secondary offering of common stock. Following amendment, on January 7, 2015 the registration statement was declared effective by the SEC and Avalanche, the Individual Exchange Act Defendants, and the underwriters priced the 2015 Offering at $59 per share. On January 7, 2015, Avalanche and the Executive Defendants filed the final prospectus for the 2015 Offering (the "**2015 Prospectus**"), which forms part of the registration statement (the 2015 Prospectus and the registration statement are collectively referred to herein as the "**2015 Registration Statement**") with the SEC, and sold 2,399,457 shares of common stock, plus the underwriters' over-allotment of an additional 359,918 shares, to the investing public. On that day, Avalanche common stock reached its Class Period high, closing at $60.08 per share. The 2015 Offering was completed on January 13, 2015 and Avalanche raised approximately $130.5 million, after deducting underwriting discounts and commissions and estimated offering expenses. *See* Avalanche Biotechnologies, Current Report (Form 8-K) (Jan. 13, 2015).

3. Progression of Phase 2a of the AVA-101 Trial

78. Mere days after the secondary offering, on January 16, 2015, Piper Jaffray published an analyst report summarizing its discussions with Avalanche management. The report stated, in relevant part, that "[m]anagement notes ***they do know or see the P2a data***, but are trying to contain expectations that the dramatic reduction in anti-VEGF antibody injection frequency in P1a may not be reproduced." Joshua E. Schimmer, Piper Jaffray, *Things We Learned This Week That You Might Not Know*, 1 (2015). Several hours later, Piper Jaffray issued a follow-up report to correct its alleged typo and instead wrote that "management notes ***they do NOT know or see the data***" for Phase 2a of the AVA-101 Trial, and further elaborated that "[t]he company is insistent that ***there is nothing they know about the trial which would change their views or expectations for the study***." Joshua E. Schimmer, Piper Jaffray, *Clarification on P2a AMD Data Expectation and Our Discussions With Management*, 1 (2015).

79. Despite Piper Jaffray and Avalanche's after-the-fact retraction, the market was not convinced, and on January 16, 2015, shares of Avalanche common stock dropped $3.19, or more than 6%, to close at $48.37 and never recovered above $50 again.

80. In fact, the Exchange Act Defendants had seen at least some of the efficacy-related data for Phase 2a of the AVA-101 Trial. Sometime around June 2013 Avalanche, Chalberg, and Blumenkranz viewed the safety data for a portion of the Phase 2a patients (***9 to be exact***) because LEI and Avalanche published an abstract in the IOVS journal regarding the safety of subretinal injection in ***17 patients*** in the AVA-101 Trial. *See* Ex. H. A year later, in its 2014 Registration Statement Avalanche stated that "***[i]nterim drug safety surveillance data received in June 2014 from this ongoing study suggests that AVA-101 continues to be well tolerated***" and that "[m]ost adverse events that have been observed to date are mild and ***not related to AVA-101 or the procedures used in the study***. ***Adverse events related to study procedures include*** subconjunctival, vitreous and retinal hemorrhage, cataract progression and eye pain. Other infrequent adverse events may be related to study procedures, including retinal tears or holes and falls." 2014 Registration Statement at 2. Then, on March 25, 2015, at Avalanche's Analyst and Investor Day Conference, Jeffrey Heier stated that "***[a] safety interim analysis was consistent with that seen in the Phase 1***, there were no adverse events related to either the drug ***or the procedure***." *Avalanche Biotechnologies Analyst and Investor Day*, Avalanche Biotechnologies (Mar. 25, 2015) http://investors.avalanchebiotech.com/phoenix.zhtml?c=253634&p=irol-EventDetails&EventId=5183324.[9]

81. The safety data "seen" in Phase 1, and the safety data collected in Phase 2a, was ophthalmic safety, which was to be determined by reviewing abnormal laboratory data and conducting an ocular examination of (a) ocular inflammation; (b) intraocular pressure; (c) ***visual acuity***; and (d) ***retinal bleeding***. Ophthalmic safety was assessed by using biomicroscopy, indirect ophthalmoscopy, ***SD OCT***, CFP, and ***FA***. *See* Ex. C at 15; Ex. E; Ex. F; Ex. G; ¶¶48-54. ***Visual***

[9] These statements are all in addition to the fact that it appeared as though LEI and Avalanche were reviewing the data on a rolling or ad hoc basis. *See* ¶¶59, 60, 68, 69.

acuity, retinal thickness, as measured by ***SD-OCT***, and leakage, as measured by ***FA***, were the three measures used to determine the secondary outcome, efficacy, *i.e.*, whether rescue injections were required. *See* Ex. C at 2; ¶48 *supra*. Thus, when Avalanche reviewed the interim study data in June 2014, it was also made aware of efficacy-related data—retinal thickness, visual acuity, CNV lesions, and the number of rescue injections required—because the data for both endpoints was measured by the same methods. ¶¶48-54. Furthermore, analysis of whether there were any adverse events related to the procedure of the study, which appeared to be ongoing throughout Phase 2a (*see* ¶¶58-60, 68, 69), necessarily required review the procedure of injecting ranibizumab into patients requiring rescue injections because AVA-101 was not working. Indeed, Avalanche and LEI stated that they were monitoring the safety of rescue injections in the 2014 IOVS abstract. *See* Ex. F.

82. In addition to these established facts demonstrating that the Exchange Act Defendants were in possession of adverse interim safety/efficacy data for Phase 2a of the AVA-101 Trial during the Class Period, the Exchange Act Defendants' attempts to "reel back" enthusiasm for the Phase 2a results further supports this inference. That is, after the IPO and the 2015 Offering, as observed by Piper Jaffray in its original January 16, 2015 analyst report, "[t]he company is focused on 'managing expectations' for the 1H15 P2a data for AVA-101 in Wet AMD and focusing on an emerging pipeline which it will highlight at its analyst event in March." Joshua E. Schimmer, Piper Jaffray, *Things We Learned This Week That you Might Not Know*, 1 (2015). Furthermore, in an e-mail interview given by Chalberg and Blumenkranz to Lowenthal Capital Partners on May 22, 2015, Avalanche greatly changed its tune from that prior to the IPO and reiterated several times that the AVA-101 Trial "is a safety study, so [the] primary goal is to ensure that there are no major safety issues. The study is not powered for statistical significance of secondary endpoints." Interview with Dr. Thomas Chalberg, CEO, and Dr. Mark Blumenkranz, Chairman of the Board, Avalanche Biopharmaceuticals, Inc., *via* e-mail (May 22, 2015), *available at* http://seekingalpha.com/article/3205796-avalanche-management-addresses-wall-streets-concerns-ahead-of-binary-catalyst. The need to "manage expectations" and refocus attention on the safety

outcome measures further demonstrates that the Exchange Act Defendants possessed negative efficacy results.

83. Tellingly, despite insisting that they were unaware of any efficacy data from Phase 2a of the AVA-101 Trial, Avalanche insiders also participated in a massive dump of Avalanche stock into the market during the Class Period. In 2015, insiders took advantage of the one exception to the still-ongoing lock-up period from the IPO and sold a total of 290,000 shares of common stock for total proceeds of $16,083,400 in the 2015 Offering. *See* ¶¶153-168 *infra*. These sales constituted 10% of the entire offering. And when the lock-up period for the 2015 Offering expired two months prior to the date when the results from Phase 2a were ultimately announced, Avalanche insiders immediately began selling more than 350,000 shares of Avalanche common stock for total proceeds of $12,908,310. *See id.*

4. The Phase 2a Topline Results

84. As promised, on June 15, 2015, Avalanche released the top-line results from Phase 2a of the AVA-101 Trial. The Company announced the following:

> Phase 2a clinical study for AVA-101 met its 12-month primary endpoint, based on ophthalmic and systemic safety, demonstrating that AVA-101 was well tolerated with a favorable safety profile in subjects with wet age-related macular degeneration (wet AMD). . . .
>
> There were no unexpected administration-related adverse events, and any events that occurred resolved without visual sequelae. . . .
>
> ***Overall, BCVA[10] mean change from baseline did show a significant difference of 11.5 letters between the treatment (+2.2 letters) and control (-9.3 letters) groups (95 percent CI, 2.3-20.7 letters)***.
>
> ***The median number of rescue injections using the protocol-specified retreatment regimen was 2 (95 percent CI, 1-6 injections) in AVA-101 treated subjects compared with 4 (95 percent CI, 3-5 injections) in the control group***. More subjects required fewer retreatments in the treatment group compared with control (19.0 percent vs. 9.1 percent with 0 injections; 33.3 percent vs. 9.1 percent with ≤1 injections; 52.4 percent vs. 9.1 percent with ≤2 injections).
>
> ***Retinal thickness mean change from baseline***, as reported by the site using automated segmentation, ***was +25 µm for AVA-101 treated subjects***

[10] "**BCVA**" is an acronym for Best Corrected Visual Acuity.

compared with -56 µm in the control group (CI for the difference, 17 to 145 µm).

85. Later that day the Company held a special conference call and continued to carry out its scheme by attempting to conceal the true implication of these results. For example, Chalberg tried to put a positive spin on the data by reiterating several times that "the key takeaway is that this was a positive Phase 2a study that met its primary objective which was to further establish the safety of AVA-101 in Wet AMD patients and also help inform future studies going forward. But in this very difficult-to-treat population, we're very encouraged to also see that AVA-101 showed promising signs of efficacy" and "[t]hese results demonstrate that AVA-101 could potentially benefit a significant portion of patients of wet AMD." Thomas W. Chalberg, CEO, Avalanche Biotechnologies, Inc., AVA-101 Phase 2a Study Results Call, 5 (June 15, 2015) (transcript on file with Bloomberg, Inc.).

86. In the end, the Exchange Act Defendants could not hide what the Company would later admit in November 2015, namely that the AVA-101 Trial "***did not [show] evidence of a complete and/or durable anti-VEGF response in the majority of subjects treated with AVA-101 as administered in the Phase 2a study***[.]" Avalanche Biotechnologies, Inc., Quarterly Report (Form 10-Q), 17 (Nov. 9, 2015). Indeed, retinal thickness, a critical anatomic efficacy measure, increased in patients treated with AVA-101 by 25 microns whereas it decreased in the control group by 56 microns. This means that AVA-101 was not only ineffective at inhibiting blood vessel growth and leakage in the retina, it fell far behind the current therapy. As a gene therapy, AVA-101 was designed to permanently change the cells in the retina to combat VEGF, eliminating the need for another injection over the patient's lifetime. However, the results from the trial showed that 10 of the 21 patients who were treated with AVA-101 received ***between 3 and 7 rescue injections***, whereas 10 of the 11 patients treated in the control group needed ***between 3 and 5 rescue injections***. *See id.* Clearly the drug did not work as intended, and for some patients was less effective than the current therapy. Finally, the improvement in visual acuity as an improvement in only 2 letters was negligible.

87. The market saw through the Exchange Act Defendants' smokescreen on the Phase 2a data and was not impressed by the results. In an article entitled "Avalanche Fails Common-Sense Test, Kicked Out of Gene Therapy Credibility Club," one commentator stated that "I'm struggling to adequately describe the awfulness of Avalanche Biotechnologies' [] performance Monday night trying to explain and defend the mediocre results of its gene therapy study in wet age-related macular degeneration (AMD)." The author pointed out that when investors looked deeper at the results, they realized the flaws, concluding that "the painful lesson here is that Avalanche's study of AVA-101 may have achieved its primary efficacy endpoint, but the gene therapy failed the more important common sense endpoint." Adam Feuerstein, *Avalanche Fails Common-Sense Test, Kicked Out of Gene Therapy Credibility Club*, The Street (June 16, 2015), http://www.thestreet.com/story/13187351/1/avalanchefailscommonsensetestkickedoutofgenetherapycredibilityclub.html. Zacks called the data "lackluster" and "weak" explaining that the "results disappointed investors[.]" *Avalanche Biotechnologies Slips on Weak AVA-101 Data*, Zacks Equity Research (June 16, 2015), http://www.zacks.com/stock/news/178460/avalanche-biotechnologies-slips-on-weak-ava101-data. An article published on investing website, the Motley Fool, explained that "[t]he problem is that the retinas of patients receiving AVA-101 thickened relative to those in the control group, casting doubt on the gene therapy's efficacy as a treatment for wet AMD[,]" "one would expect the *exact* opposite result if AVA-101 was truly helping patients maintain their visual acuity." George Budwell, *Why Avalanche Biotechnologies, Inc. Stock Collapsed Today*, Motley Fool (June 16, 2015), http://www.fool.com/investing/general/2015/06/16/why-avalanche-biotechnologies-inc-stock-collapsed.aspx.

88. On this news shares of Avalanche common stock plummeted $21.83, or more than 56%, to close on June 16, 2015 at $17.05 per share.

89. On July 23, 2015, Avalanche announced that Chalberg would resign as CEO and president and as a member of the Board of Directors effective that day. *See* Avalanche Biotechnologies, Inc., Current Report (Form 8-K) (July 23, 2015). He was, however, to remain as a consultant for Avalanche and member of the Scientific Advisory Board. *See id.*

E. The AVA-101 Trial Is Abandoned

90. Throughout the Class Period, Avalanche and the Individual Exchange Act Defendants represented that after announcing data from Phase 2a of the AVA-Trial in the middle of 2015, Avalanche would conduct Phase 2b of the AVA-101 Trial "in the second half of 2015." Avalanche Biotechnologies Inc., Annual Report (Form 10-K), 26 (Mar. 5, 2015).

91. Avalanche and the Individual Exchange Act Defendants represented to investors that this plan remained intact even after the lackluster results from Phase 2a, stating during the conference call on June 15, 2015 that "we're excited and on track to start a Phase 2b study later this year." Thomas W. Chalberg, CEO, Avalanche Biotechnologies, Inc., AVA-101 Phase 2a Study Results Call, 7 (June 15, 2015) (transcript on file with Bloomberg, Inc.).

92. However, less than two months later, on August 13, 2015, Avalanche reversed course and announced that it would not be proceeding with Phase 2b of the AVA-101 Trial in the second half of 2015 and would instead "conduct additional preclinical studies to investigate optimal dose and delivery of AVA-101 and AVA-201 versus standard of care anti-VEGF protein therapy to select the best gene therapy product candidate for wet AMD to advance back into the clinic." Avalanche Biotechnologies, Inc., Current Report (Form 8-K) (Aug. 13, 2015).

93. On this news, shares of Avalanche common stock dropped $3.82, or more than 27%, to close on August 14, 2015 at $10.01 per share.

94. On October 19, 2015, Avalanche announced that Linda Bain would resign from her position as CFO effective November 17, 2015. *See* Avalanche Biotechnologies, Inc., Current Report (Form 8-K) (Oct. 19, 2015).

III. CLASS PERIOD STATEMENTS AND EVENTS

95. On or about May 30, 2014, Avalanche filed with the SEC its registration statement on Form S-1 (Registration No 333-197133). Following amendment, on July 30, 2014, the registration statement was declared effective by the SEC and Avalanche, the Individual Exchange Act Defendants, and the underwriters priced the IPO at $17 per share. On July 31, 2014, the first day of the Class Period, Avalanche and the Individual Exchange Act Defendants filed the 2014

Prospectus with the SEC (the 2014 Prospectus was incorporated into the registration statement and together they formed the "2014 Registration Statement"), and sold 6,900,000 shares of common stock to the investing public for total proceeds of $106.8 million after deducting underwriting discounts, commissions, and expenses. The IPO was completed on August 5, 2014. Defendants Chalberg, Bain, Blumenkranz, and Schwartz, *inter alia*, signed the 2014 Registration Statement.

96. As described below, the 2014 Registration Statement contained untrue statements of material facts or omitted to state other facts necessary to make the statements made not misleading, and was not prepared in accordance with the rules and regulations regarding is preparation.

97. There were two general categories of misstatements and omissions: (1) statements and omissions concerning AVA-101 and the data from the AVA-101 Trial viewed by the Company and the Individual Exchange Act Defendants prior to the IPO; and (2) statements and omissions regarding the risks facing the Company arising from the efficacy, or lack thereof, of AVA-101.

98. For example, in regard to the data viewed by the Company and the Individual Exchange Act Defendants prior to the IPO, Avalanche, Chalberg, Bain, Blumenkranz, and Schwartz stated in the 2014 Registration Statement:

> We are currently conducting a Phase 2a trial for AVA-101 at LEI with 32 additional wet AMD subjects. ***Interim drug safety surveillance data received in June 2014 from this ongoing study suggests that AVA-101 continues to be well tolerated***. Most adverse events that have been observed to date are mild and not related to AVA-101 or the procedures used in the study. Adverse events related to study procedures include subconjunctival, vitreous and retinal hemorrhage, cataract progression and eye pain. Other infrequent adverse events may be related to study procedures, including retinal tears or holes and falls. A small number of adverse events may be possibly related to AVA-101, including inflammation and light chain analysis increase, but these were considered mild and transient and have not been associated with vision loss. We expect to receive top-line data from this ongoing Phase 2a trial in mid-2015.
>
> * * *
>
> We are currently conducting a Phase 2a trial for AVA-101 in wet AMD. ***Interim drug safety surveillance data received in June 2014 from this ongoing study suggests that AVA-101 continues to be well tolerated. We expect to receive top-line data from this ongoing Phase 2a trial in mid-2015.***

99. In regard to the risks facing the Company at the time of the offering, Avalanche, Chalberg, Bain, Blumenkranz, and Schwartz stated in the 2014 Registration Statement:

> ***Our business currently depends substantially on the success of AVA-101, which is still under development. If we are unable to obtain regulatory approval for, or successfully commercialize, AVA-101, our business will be materially harmed.***
>
> * * *
>
> ***Successful continued development and ultimate regulatory approval of AVA-101 is critical for our future business success. . . .***
>
> ***The future regulatory and commercial success of this product candidate is subject to a number of risks, including the following:***
>
> > ***we may not be able to provide evidence of efficacy and safety for AVA-101***;
> >
> > ***the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory bodies for marketing approval;***
>
> * * *
>
> ***Our ability to commercialize our product candidates effectively will depend on several factors, including the following:***
>
> > ***successful completion of preclinical studies and clinical trials, including the ability to demonstrate safety and efficacy of our product candidates***
>
> * * *
>
> ***[S]uccess in early clinical trials does not mean that later clinical trials will be successful, because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing.***
>
> * * *
>
> ***If our proprietary vectors are not shown to be safe and effective in targeting retinal tissue, we may not realize the value of our investment in directed evolution technology***.
>
> * * *
>
> In addition, ***success in early clinical trials does not mean that later clinical trials will be successful, because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing***. . . .

> ***We cannot be certain that any of our planned clinical trials will be successful, and any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.***
>
> * * *
>
> ***The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:***
>
> > ***we or any of our future development partners may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe and effective for any indication***;
> >
> > ***the results of clinical trials may not demonstrate the safety or efficacy required by such authorities for approval***;
> >
> > * * *
>
> ***The degree of market acceptance of our product candidates will depend on a number of factors, including:***
>
> > ***demonstration of clinical efficacy and safety compared to other more-established products;***
> >
> > * * *
>
> ***Reimbursement by a third-party payer may depend upon a number of factors including the third-party payer's determination that use of a product candidate is:***
>
> > ***safe, effective and medically necessary***;
> >
> > * * *
>
> ***All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities***.

100. The foregoing statements in ¶¶98-99 were materially false and/or misleading because they omitted and/or misrepresented the following adverse facts that existed and were known or recklessly disregarded by the speaker at the time of each statement:

a) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were experiencing significant thickening of the retina, evidencing that AVA-101 was not effective in treating Wet AMD;

b) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were requiring multiple rescue injections, evidencing that AVA-101 was not effective in treating Wet AMD;

c) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were not experiencing significant improvements in visual acuity scores required to justify the increased risk of adverse safety events, evidencing that AVA-101 was not effective in treating Wet AMD; and

d) As a result, Avalanche's business and financial prospects concerning AVA-101 were not what the speakers had led the market to believe they were.

101. In fact, the 2014 Registration Statement ***in its entirety*** was misleading because, despite the fact that the Company was selling its shares to the public and had a duty to disclose all material non-public information under Rule 10b-5, Avalanche omitted the following adverse facts that then existed and were known or recklessly disregarded by the Company at the time of the statement:

a) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were experiencing significant thickening of the retina, evidencing that AVA-101 was not effective in treating Wet AMD;

b) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were requiring multiple rescue injections, evidencing that AVA-101 was not effective in treating Wet AMD;

c) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were not experiencing significant improvements in visual acuity scores required to justify the increased risk of adverse safety events, evidencing that AVA-101 was not effective in treating Wet AMD; and

d) As a result, Avalanche's business and financial prospects concerning AVA-101 were not what the speakers had led the market to believe they were.

102. On July 30, 2014, Avalanche priced its IPO at $17.00 per share. Avalanche's stock price closed at $27.99 on the day of the IPO, climbing nearly 40% in one day, even after being priced above expectations.

103. On September 12, 2014, Avalanche filed its Form 10-Q for the quarter ending June 30, 2014 (the "2Q 2014 Form 10-Q"), signed by defendant Bain. In regard to the efficacy of AVA-101, Avalanche and Bain stated in the 2Q 2014 Form 10-Q, in relevant part:

> ***We believe that this product candidate could transform the treatment paradigm and address the unmet need in the large wet AMD market***, which is estimated to be over $6.0 billion worldwide.

104. In the Risk Factors section, Avalanche and Bain stated in the 2Q 2014 Form 10-Q in relevant part:

> ***Our business currently depends substantially on the success of AVA-101, which is still under development. If we are unable to obtain regulatory approval for, or successfully commercialize, AVA-101, our business will be materially harmed***. . . .
>
> ***The future regulatory and commercial success of this product candidate is subject to a number of risks, including the following***:
>
> > ***we may not be able to provide evidence of efficacy and safety for AVA-101***;
> >
> > ***the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory bodies for marketing approval***;
> >
> > * * *
>
> ***Our ability to commercialize our product candidates effectively will depend on several factors, including the following***:
>
> > ***successful completion of preclinical studies and clinical trials, including the ability to demonstrate safety and efficacy of our product candidates***;
> >
> > * * *
>
> ***[S]uccess in early clinical trials does not mean that later clinical trials will be successful, because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing***.
>
> * * *

> ***If our proprietary vectors are not shown to be safe and effective in targeting retinal tissue, we may not realize the value of our investment in directed evolution technology.***
>
> * * *
>
> ***We cannot be certain that any of our planned clinical trials will be successful, and any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.***
>
> * * *
>
> ***The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:***
>
> > ***we or any of our future development partners may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe and effective for any indication***;
> >
> > ***the results of clinical trials may not demonstrate the safety or efficacy required by such authorities for approval;***
> >
> > * * *
>
> ***The degree of market acceptance of our product candidates will depend on a number of factors, including:***
>
> > ***demonstration of clinical efficacy and safety compared to other more-established products;***
> >
> > * * *
>
> ***Reimbursement by a third-party payer may depend upon a number of factors including the third-party payer's determination that use of a product candidate is:***
>
> > ***safe, effective and medically necessary***;
> >
> > * * *
>
> ***All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities***.

105. Additionally, the 2Q 2014 Form 10-Q contained certifications pursuant to the Sarbanes-Oxley Act 2001 ("SOX") signed by CEO Chalberg and CFO Bain stating that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a

material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report[.]"

106. The foregoing statements in ¶¶103-105 were materially false and/or misleading because they omitted and/or misrepresented the following adverse facts that existed and were known or recklessly disregarded by the speaker at the time of each statement:

a) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were experiencing significant thickening of the retina, evidencing that AVA-101 was not effective in treating Wet AMD;

b) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were requiring multiple rescue injections, evidencing that AVA-101 was not effective in treating Wet AMD;

c) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were not experiencing significant improvements in visual acuity scores required to justify the increased risk of adverse safety events, evidencing that AVA-101 was not effective in treating Wet AMD; and

d) As a result, Avalanche's business and financial prospects concerning AVA-101 were not what the speakers had led the market to believe they were.

107. On October 14, 2014, Avalanche filed with the SEC a registration statement on Form S-8 to register 7,681,165 shares of Avalanche common stock issuable under the Company's Amended and Restated 2006 Equity Incentive Plan, the 2014 Equity Incentive Award Plan, and the 2014 Employee Stock Purchase Plan. The registration statement was filed by defendants Chalberg, Bain, and Blumenkranz. The registration statement incorporated by reference the 2014 Registration Statement and the 2Q 2014 Form 10-Q.

108. The foregoing statements in ¶107 were materially false and/or misleading because they omitted and/or misrepresented the following adverse facts that existed and were known or recklessly disregarded by the speaker at the time of each statement:

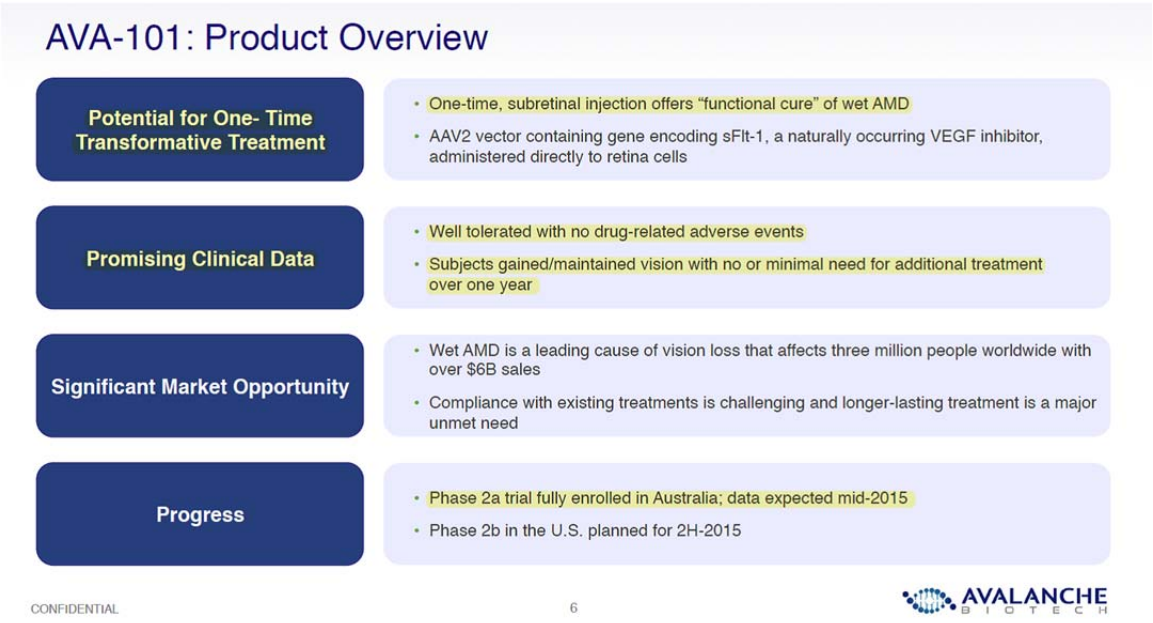
a) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were experiencing significant thickening of the retina, evidencing that AVA-101 was not effective in treating Wet AMD;

b) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were requiring multiple rescue injections, evidencing that AVA-101 was not effective in treating Wet AMD;

c) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were not experiencing significant improvements in visual acuity scores required to justify the increased risk of adverse safety events, evidencing that AVA-101 was not effective in treating Wet AMD; and

d) As a result, Avalanche's business and financial prospects concerning AVA-101 were not what the speakers had led the market to believe they were.

109. On October 16, 2014, defendant Chalberg presented on behalf of Avalanche at the Ophthalmology Innovation Summit at the American Academy of Ophthalmology ("AAO") 2014 Annual Meeting. The presentation contained the following slide:



110. The foregoing statements in ¶109 were materially false and/or misleading because they omitted and/or misrepresented the following adverse facts that existed and were known or recklessly disregarded by the speaker at the time of each statement:

a) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were experiencing significant thickening of the retina, evidencing that AVA-101 was not effective in treating Wet AMD;

b) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were requiring multiple rescue injections, evidencing that AVA-101 was not effective in treating Wet AMD;

c) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were not experiencing significant improvements in visual acuity scores required to justify the increased risk of adverse safety events, evidencing that AVA-101 was not effective in treating Wet AMD; and

d) As a result, Avalanche's business and financial prospects concerning AVA-101 were not what the speakers had led the market to believe they were.

111. On November 7, 2014, defendant Chalberg presented to AAO an update on Avalanche's pipeline of products as part of the Company's Ocular BioFactory Tour. Chalberg gave a Power-point presentation that contained the same slide set forth in ¶109. During the presentation, Chalberg also stated, in relevant part:

> ***And so through this early trial data that we find very encouraging, we're looking forward to following up more patients,*** and we'll see the Phase IIa study data in the middle of next year.

112. The foregoing statements in ¶111 were materially false and/or misleading because they omitted and/or misrepresented the following adverse facts that existed and were known or recklessly disregarded by the speaker at the time of each statement:

a) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were experiencing significant thickening of the retina, evidencing that AVA-101 was not effective in treating Wet AMD;

b) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were requiring multiple rescue injections, evidencing that AVA-101 was not effective in treating Wet AMD;

c) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were not experiencing significant improvements in visual acuity scores required to justify the increased risk of adverse safety events, evidencing that AVA-101 was not effective in treating Wet AMD; and

d) As a result, Avalanche's business and financial prospects concerning AVA-101 were not what the speakers had led the market to believe they were.

113. On November 12, 2014, Avalanche filed its Form 10-Q for the quarter ending September 30, 2014 (the "3Q 2014 Form 10-Q"), signed by defendant Bain. The 3Q 2014 Form 10-Q contained a SOX certification signed by defendants Chalberg and Bain containing the same form and content as the certification accompanying the 2Q 2014 Form 10-Q, set forth in ¶105. In regard to the AVA-101 Trial, Avalanche and Bain stated in the 3Q 2014 Form 10-Q, in relevant part:

> ***We believe that this product candidate could transform the treatment paradigm and address the unmet need in the large wet AMD market***, which is estimated to be over $6.0 billion worldwide. . . .
>
> In that Phase 1 trial, AVA-101 was well tolerated with no drug-related adverse events. In addition, subjects treated with AVA-101 showed meaningful improvement in their visual acuity test scores (up to 15 letter improvement on an eye chart from baseline), and most subjects did not receive any rescue injections of standard-of-care therapy (required for subjects exhibiting disease progression) during the one-year trial period.We are currently conducting a Phase 2a trial for AVA-101 at LEI with 32 additional wet AMD subjects. ***Interim drug safety surveillance data received in June 2014 from this ongoing study suggests that AVA-101 continues to be well tolerated***. . . . We expect to receive top-line data from this ongoing Phase 2a trial in mid-2015.

114. The 3Q 2014 Form 10-Q contained a Risk Factors section with statements identical to those in the 2Q 2014 Form 10-Q set forth in ¶102 above.

115. The foregoing statements in ¶¶113-114 were materially false and/or misleading because they omitted and/or misrepresented the following adverse facts that existed and were known or recklessly disregarded by the speaker at the time of each statement:

a) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were experiencing significant thickening of the retina, evidencing that AVA-101 was not effective in treating Wet AMD;

b) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were requiring multiple rescue injections, evidencing that AVA-101 was not effective in treating Wet AMD;

c) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were not experiencing significant improvements in visual acuity scores required to justify the increased risk of adverse safety events, evidencing that AVA-101 was not effective in treating Wet AMD; and

d) As a result, Avalanche's business and financial prospects concerning AVA-101 were not what the speakers had led the market to believe they were.

116. On or about December 18, 2014, Avalanche filed with the SEC its registration statement on Form S-1 (Registration No 333-201388) for a secondary offering of common stock. Following amendment, on January 7, 2015 the registration statement was declared effective by the SEC and Avalanche and the underwriters priced the 2015 Offering at $59 per share. On January 7, 2015, Avalanche and the Individual Exchange Act Defendants filed the 2015 Prospectus, which forms part of the registration statement (the 2015 Prospectus and 2015 Registration Statement are collectively referred to herein as the "2015 Registration Statement") with the SEC, and sold 2,399,457 shares of common stock, plus the underwriters' over-allotment of an additional 359,918 shares, to the investing public. The 2015 Offering was completed on January 13, 2015 and raised approximately $130.5 million. Defendants Chalberg, Bain, Blumenkranz, and Schwartz, *inter alia*, signed the 2015 Registration Statement.

117. The 2015 Registration Statement contained statements nearly identical to the statements in the 2014 Registration Statement as set forth above in ¶¶98-99. For example, in regard to the data viewed by the Company and the Individual Exchange Act Defendants, Avalanche, Chalberg, Bain, Blumenkranz, and Schwartz stated in the 2015 Registration Statement:

> We are currently conducting a Phase 2a trial for AVA-101 at LEI with 32 additional wet AMD subjects. ***Interim drug safety surveillance data received in June 2014 from this ongoing study suggests that AVA-101 continues to be well tolerated.*** Most adverse events that have been observed to date are mild and not related to AVA-101 or the procedures used in the study. Adverse events related to study procedures include subconjunctival, vitreous and retinal hemorrhage, cataract progression and eye pain. Other infrequent adverse events may be related to study procedures, including retinal tears or holes and falls. A small number of adverse events may be possibly related to AVA-101, including inflammation and light chain analysis increase, but these were considered mild and transient and have not been associated with vision loss. We expect to receive top-line data from this ongoing Phase 2a trial in mid-2015.
>
> * * *
>
> We are currently conducting a Phase 2a trial for AVA-101 in wet AMD. ***Interim drug safety surveillance data received in June 2014 from this ongoing study suggests that AVA-101 continues to be well tolerated. We expect to receive top-line data from this ongoing Phase 2a trial in mid-2015***.

118. In regard to the risks facing the Company at the time of the 2015 Offering, Avalanche, Chalberg, Bain, Blumenkranz, and Schwartz stated in the 2015 Registration Statement:

> ***Our business currently depends substantially on the success of AVA-101, which is still under development. If we are unable to obtain regulatory approval for, or successfully commercialize, AVA-101, our business will be materially harmed.***
>
> * * *
>
> ***Successful continued development and ultimate regulatory approval of AVA-101 is critical for our future business success…***
>
> ***The future regulatory and commercial success of this product candidate is subject to a number of risks, including the following:***
>
> > ***we may not be able to provide evidence of efficacy and safety for AVA-101;***

> ***the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory bodies for marketing approval;***
>
> * * *
>
> ***[S]uccess in early clinical trials does not mean that later clinical trials will be successful, because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing.***
>
> * * *
>
> ***If our proprietary vectors are not shown to be safe and effective in targeting retinal tissue, we may not realize the value of our investment in directed evolution technology.***
>
> * * *
>
> In addition, ***success in early clinical trials does not mean that later clinical trials will be successful, because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing…***
>
> ***We cannot be certain that any of our planned clinical trials will be successful, and any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.***
>
> * * *
>
> ***The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:***
>
> ***we or any of our future development partners may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe and effective for any indication;***
>
> ***the results of clinical trials may not demonstrate the safety or efficacy required by such authorities for approval;***
>
> * * *
>
> ***The degree of market acceptance of our product candidates will depend on a number of factors, including:***
>
> ***demonstration of clinical efficacy and safety compared to other more-established products;***
>
> * * *

> ***Reimbursement by a third-party payer may depend upon a number of factors including the third-party payer's determination that use of a product candidate is:***
>
> ***safe, effective and medically necessary***;
>
> * * *
>
> ***All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities***.

119. The foregoing statements in ¶¶117-118 were materially false and/or misleading because they omitted and/or misrepresented the following adverse facts that existed and were known or recklessly disregarded by the speaker at the time of each statement:

a) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were experiencing significant thickening of the retina, evidencing that AVA-101 was not effective in treating Wet AMD;

b) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were requiring multiple rescue injections, evidencing that AVA-101 was not effective in treating Wet AMD;

c) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were not experiencing significant improvements in visual acuity scores required to justify the increased risk of adverse safety events, evidencing that AVA-101 was not effective in treating Wet AMD; and

d) As a result, Avalanche's business and financial prospects concerning AVA-101 were not what the speakers had led the market to believe they were.

120. In fact, the 2015 Registration Statement in ***its entirety*** was misleading because, despite the fact that the Company, Chalberg, Blumenkranz, and Schwartz were selling their shares to the public and had a duty to disclose all material non-public information under Rule 10b-5, Avalanche omitted the following adverse facts that then existed and were known or recklessly disregarded by the Company at the time of the statement:

a) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were experiencing significant thickening of the retina, evidencing that AVA-101 was not effective in treating Wet AMD;

b) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were requiring multiple rescue injections, evidencing that AVA-101 was not effective in treating Wet AMD;

c) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were not experiencing significant improvements in visual acuity scores required to justify the increased risk of adverse safety events, evidencing that AVA-101 was not effective in treating Wet AMD; and

d) As a result, Avalanche's business and financial prospects concerning AVA-101 were not what the speakers had led the market to believe they were.

121. On January 16, 2015, Piper Jaffray published a report summarizing its discussions with Avalanche management. In regard to the data from Phase 2a of the AVA-101 Trial, the report stated, in relevant part:

> The company is focused on 'managing expectations' for the 1H15 P2a data for AVA-101 in wet AMD and focusing on an emerging pipeline which it will highlight at its analyst event in March. ***Management notes they do know or see the P2a data, but are trying to contain expectations that the dramatic reduction in anti-VEGF antibody injection frequency in P1a may not be reproduced***.

122. Shortly thereafter, Piper Jaffray issued a follow-up report to correct what it alleges it "erroneously wrote." The report stated that they meant to write that "'***management notes they do NOT know or see the data***' ***for the 1H15 P2a AVA-101 wet AMD data***." The report then reiterated that "***Management notes they don't know the data: The company is insistent that there is nothing they know about the trial which would change their views or expectations for the study***."

123. The foregoing statements in ¶122 were materially false and/or misleading because Avalanche omitted and/or misrepresented the following adverse facts that existed and were known or recklessly disregarded by the speaker at the time of each statement:

a) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were experiencing significant thickening of the retina, evidencing that AVA-101 was not effective in treating Wet AMD;

b) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were requiring multiple rescue injections, evidencing that AVA-101 was not effective in treating Wet AMD;

c) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were not experiencing significant improvements in visual acuity scores required to justify the increased risk of adverse safety events, evidencing that AVA-101 was not effective in treating Wet AMD; and

d) As a result, Avalanche's business and financial prospects concerning AVA-101 were not what the speakers had led the market to believe they were.

124. Despite Piper Jaffray and Avalanche's attempt at damage control, the damage was already done. On January 16, 2015, shares of Avalanche common stock dropped $3.19, or more than 6%, to close at $48.37 and never recovered above $50 again.

125. On March 5, 2015, Cowen and Company published a report summarizing the highlights from a lunch held with Chalberg and Bain. In regarding to Phase 2a of the AVA-101 Trial, the report stated in relevant part:

> ***The trial included an interim safety analysis which was conducted in June of 2014, several months after dosing in most patients. Management noted that this safety analysis was successfully passed, with no serious or worrisome adverse events detected. As the study is ongoing, management said that it does not have knowledge of any adverse event or efficacy data other that the safety data from the June 2014 safety analysis***. Nonetheless, management did say that the trial has a pharmacovigilance committee which monitors adverse events. Avalanche would be informed of any serious complications made known to the pharmacovigilance committee. Thus far the committee has not been notified of any serious adverse events in the trial. With nearly all patients

> at least nine months past their AVA-101 injection, we think this bodes well for AVA-101's safety profile in the Ph. IIa.

126. The foregoing statements in ¶125 were materially false and/or misleading because they omitted and/or misrepresented the following adverse facts that existed and were known or recklessly disregarded by the speaker at the time of each statement:

a) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were experiencing significant thickening of the retina, evidencing that AVA-101 was not effective in treating Wet AMD;

b) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were requiring multiple rescue injections, evidencing that AVA-101 was not effective in treating Wet AMD;

c) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were not experiencing significant improvements in visual acuity scores required to justify the increased risk of adverse safety events, evidencing that AVA-101 was not effective in treating Wet AMD; and

d) As a result, Avalanche's business and financial prospects concerning AVA-101 were not what the speakers had led the market to believe they were.

127. On March 5, 2015, Avalanche filed its Form 10-K for the fiscal year ending December 31, 2015 ("2015 Form 10-K), signed by defendants Chalberg, Bain, Blumenkranz, and Schwartz *inter alia*. The 2015 Form 10-K contained a SOX certification signed by defendants Chalberg and Bain containing the same form and content as the certification accompanying the 2Q 2014 Form 10-Q, set forth in ¶105. In regard to the data viewed by Avalanche and the Individual Exchange Act Defendants Chalberg, Bain, Blumenkranz, and Schwartz stated:

> We are currently conducting a Phase 2a trial for AVA-101 at LEI with 32 additional wet AMD subjects. ***Interim drug safety surveillance data received in June 2014 from this ongoing study suggests that AVA-101 continues to be well tolerated***. Most adverse events that have been observed to date are mild and not related to AVA-101 or the procedures used in the study. Adverse events related to study procedures include subconjunctival, vitreous and retinal hemorrhage, cataract progression and

> eye pain. Other infrequent adverse events may be related to study procedures, including retinal tears or holes and falls. A small number of adverse events may be possibly related to AVA-101, including inflammation and light chain analysis increase, but these were considered mild and transient and have not been associated with vision loss. We expect to receive top-line data from this ongoing Phase 2a trial in mid-2015.

128. In regard to the risks facing the Company at the end of 2015, Avalanche, Chalberg, Bain, Blumenkranz, and Schwartz stated in the 2015 Form 10-K:

> ***Our business currently depends substantially on the success of AVA-101, which is still under development. If we are unable to obtain regulatory approval for, or successfully commercialize, AVA-101, our business will be materially harmed.***
>
> * * *
>
> ***Successful continued development and ultimate regulatory approval of AVA-101 is critical for our future business success. . . .***
>
> ***The future regulatory and commercial success of this product candidate is subject to a number of risks, including the following:***
>
> > ***we may not be able to provide evidence of efficacy and safety for AVA-101***;
> >
> > ***the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory bodies for marketing approval;***
>
> * * *
>
> ***Our ability to commercialize our product candidates effectively will depend on several factors, including the following:***
>
> > ***successful completion of preclinical studies and clinical trials, including the ability to demonstrate safety and efficacy of our product candidates***
>
> * * *
>
> ***[S]uccess in early clinical trials does not mean that later clinical trials will be successful, because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing.***
>
> * * *

If our proprietary vectors are not shown to be safe and effective in targeting retinal tissue, we may not realize the value of our investment in directed evolution technology.

* * *

In addition, ***success in early clinical trials does not mean that later clinical trials will be successful, because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing***. . . .

We cannot be certain that any of our planned clinical trials will be successful, and any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.

* * *

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

> ***we or any of our future development partners may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe and effective for any indication***;
>
> ***the results of clinical trials may not demonstrate the safety or efficacy required by such authorities for approval***;

* * *

The degree of market acceptance of our product candidates will depend on a number of factors, including:

> ***demonstration of clinical efficacy and safety compared to other more-established products;***

* * *

Reimbursement by a third-party payer may depend upon a number of factors including the third-party payer's determination that use of a product candidate is:

> ***safe, effective and medically necessary***;

* * *

All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities.

129. The foregoing statements in ¶¶127-128 were materially false and/or misleading because they omitted and/or misrepresented the following adverse facts that existed and were known or recklessly disregarded by the speaker at the time of each statement:

a) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were experiencing significant thickening of the retina, evidencing that AVA-101 was not effective in treating Wet AMD;

b) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were requiring multiple rescue injections, evidencing that AVA-101 was not effective in treating Wet AMD;

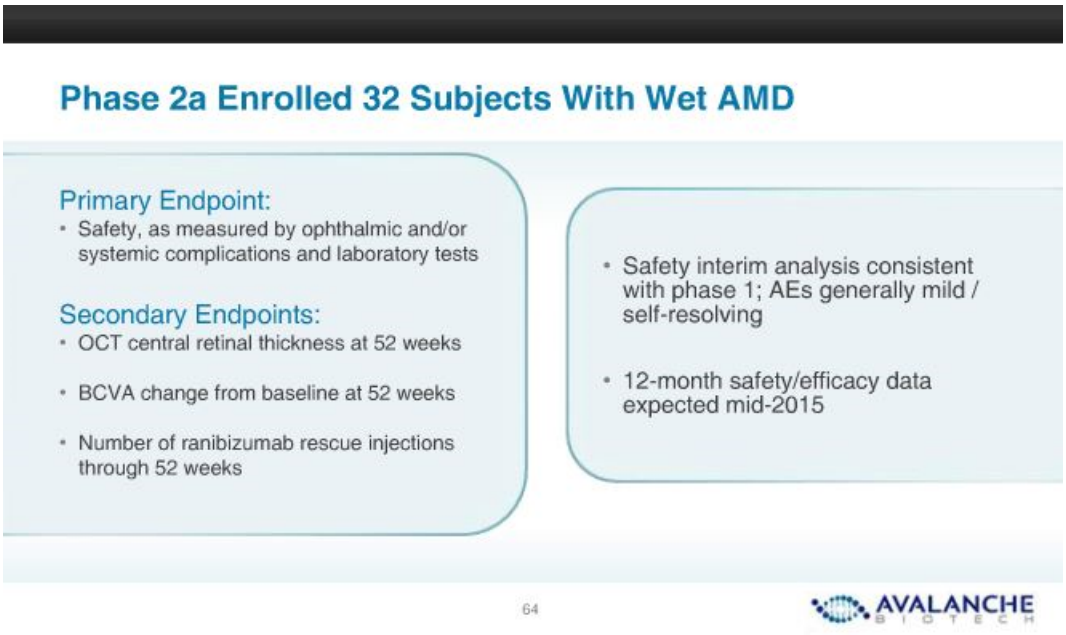
c) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were not experiencing significant improvements in visual acuity scores required to justify the increased risk of adverse safety events, evidencing that AVA-101 was not effective in treating Wet AMD; and

d) As a result, Avalanche's business and financial prospects concerning AVA-101 were not what the speakers had led the market to believe they were.

130. On March 25, 2015, Avalanche hosted an analyst and investor day conference entitled, "Transforming the Landscape for Patients with Eye Disease." Chalberg and Bain were also present at the conference. In regard to Phase 2a of the AVA-101 Trial, Jeffrey Heier, the Director of Retina Research at Ophthalmic Consultants of Boston, stated:

> A safety interim analysis was consistent with that seen in the Phase 1, there were no adverse events related to either the drug or the procedure. And 12 month safety and efficacy data should be presented later this year.

131. The presentation also contained the following slides:



132. On April 14, 2015, Avalanche filed with the SEC a registration statement on Form S-8 to register an additional 1,137,701 shares of Avalanche common stock issuable under the Company's 2014 Equity Incentive Award Plan and the 2014 Employee Stock Purchase Plan. The registration statement was filed by defendants Chalberg, Bain, Blumenkranz, and Schwartz. The registration statement incorporated by reference the 2015 Form 10-K. The 2015 Form 10-K contained a SOX certification signed by defendants Chalberg and Bain containing the same form and content as the certification accompanying the 2Q 2014 Form 10-Q, set forth in ¶105 and also contained the misleading statements set forth above in ¶¶127-128.

133. The foregoing statements in ¶132 were materially false and/or misleading because they omitted and/or misrepresented the following adverse facts that existed and were known or recklessly disregarded by the speaker at the time of each statement:

a) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were experiencing significant thickening of the retina, evidencing that AVA-101 was not effective in treating Wet AMD;

b) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were requiring multiple rescue injections, evidencing that AVA-101 was not effective in treating Wet AMD;

c) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were not experiencing significant improvements in visual acuity scores required to justify the increased risk of adverse safety events, evidencing that AVA-101 was not effective in treating Wet AMD; and

d) As a result, Avalanche's business and financial prospects concerning AVA-101 were not what the speakers had led the market to believe they were.

134. On May 13, 2015, Avalanche also filed its Form 10-Q for the quarter ended March 31, 2015 ("1Q 2015 Form 10-Q), signed by defendant Bain. The 1Q 2015 Form 10-Q contained a SOX certification signed by defendants Chalberg and Bain containing the same form and content as the certification accompanying the 2Q 2014 Form 10-Q, set forth in ¶105. In the 1Q 2015 Form 10-Q Avalanche and Bain stated the following:

> ***We believe that this product candidate could transform the treatment paradigm and address the unmet need in the large wet AMD market***, which is estimated to be over $6.0 billion worldwide.
>
> * * *
>
> ***Our business currently depends substantially on the success of AVA-101, which is still under development. If we are unable to obtain regulatory approval for, or successfully commercialize, AVA-101, our business will be materially harmed***. . . .
>
> ***The future regulatory and commercial success of this product candidate is subject to a number of risks, including the following***:
>
> > ***we may not be able to provide evidence of efficacy and safety for AVA-101***;
> >
> > ***the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory bodies for marketing approval***;
> >
> > * * *
>
> ***Our ability to commercialize our product candidates effectively will depend on several factors, including the following***:
>
> > ***successful completion of preclinical studies and clinical trials, including the ability to demonstrate safety and efficacy of our product candidates***;
> >
> > * * *

[S]uccess in early clinical trials does not mean that later clinical trials will be successful, because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing.

* * *

If our proprietary vectors are not shown to be safe and effective in targeting retinal tissue, we may not realize the value of our investment in directed evolution technology.

* * *

We cannot be certain that any of our planned clinical trials will be successful, and any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.

* * *

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

> ***we or any of our future development partners may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe and effective for any indication;***
>
> ***the results of clinical trials may not demonstrate the safety or efficacy required by such authorities for approval;***

* * *

The degree of market acceptance of our product candidates will depend on a number of factors, including:

> ***demonstration of clinical efficacy and safety compared to other more established products;***

* * *

Reimbursement by a third-party payer may depend upon a number of factors including the third-party payer's determination that use of a product candidate is:

> ***safe, effective and medically necessary;***

* * *

All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities.

135. The foregoing statements in ¶134 were materially false and/or misleading because they omitted and/or misrepresented the following adverse facts that existed and were known or recklessly disregarded by the speaker at the time of each statement:

a) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were experiencing significant thickening of the retina, evidencing that AVA-101 was not effective in treating Wet AMD;

b) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were requiring multiple rescue injections, evidencing that AVA-101 was not effective in treating Wet AMD;

c) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were not experiencing significant improvements in visual acuity scores required to justify the increased risk of adverse safety events, evidencing that AVA-101 was not effective in treating Wet AMD; and

d) As a result, Avalanche's business and financial prospects concerning AVA-101 were not what the speakers had led the market to believe they were.

136. At no point during the Class Period did the makers of these statements ever correct or update their statements.

IV. POST CLASS PERIOD EVENTS

137. After the market closed on June 15, 2015, Avalanche announced the top-line results from Phase 2a its AVA-101 Trial. In regard to the primary endpoint, safety, the Company explained that Avalanche's "Phase 2a clinical study for AVA-101 met its 12-month primary endpoint, based on ophthalmic and systemic safety, demonstrating that AVA-101 was well tolerated with a favorable safety profile in subjects with wet age-related macular degeneration[.]" In regard to the secondary endpoints for Phase 2a, the Company stated the following:

> ***Overall, BCVA mean change from baseline did show a significant difference of 11.5 letters between the treatment (+2.2 letters) and control (-9.3 letters) groups (95 percent CI, 2.3-20.7 letters)***.

> More AVA-101 treated subjects improved or maintained stable vision (>-5 letters) with a low number (≤2) of rescue treatments. Specifically, 23.8 percent (treated) vs. 9.1 percent (control) maintained stable vision with ≤1 rescue injections, and a significant number of AVA-101 treated subjects (42.9 percent) improved or maintained stable vision with ≤2 rescue injections compared with subjects in the control group (9.1 percent).
>
> BCVA improvement of ≥10 letters with ≤2 rescue injections was observed in 23.8 percent of treated subjects and 0 percent of subjects in the control group.
>
> ***The median number of rescue injections using the protocol-specified retreatment regimen was 2 (95 percent CI, 1-6 injections) in AVA-101 treated subjects compared with 4 (95 percent CI, 3-5 injections) in the control group***. More subjects required fewer retreatments in the treatment group compared with control (19.0 percent vs. 9.1 percent with 0 injections; 33.3 percent vs. 9.1 percent with ≤1 injections; 52.4 percent vs. 9.1 percent with ≤2 injections).
>
> ***Retinal thickness mean change from baseline***, as reported by the site using automated segmentation, ***was +25 µm for AVA-101 treated subjects compared with -56 µm in the control group*** (CI for the difference, 17 to 145 µm). Additional evaluation of SD-OCT images by an image reading center are ongoing.

138. Later that day the Company held a special conference call to discuss the top-line data and further reiterated several times that "the key takeaway is that this was a positive Phase 2a study that met its primary objective which was to further establish safety of AVA-101 in wet AMD patients and also help inform future studies going forward . . . we're very encouraged to also see that AVA-101 showed promising signs of efficacy[.]" The Company, Barone, and Chalberg also provided more detail regarding the AVA-101 Trial results, stating the following:

> [Barone]: The primary endpoint was safety and tolerability of AVA-101 as measured by ophthalmic and/or systemic complications and laboratory tests. . . . The study met its primary endpoint. . . .
>
> [D]ata from secondary endpoints suggest evidence of biological activity in subjects treated with AVA-101. ***Overall, mean change in best corrected visual acuity from baseline showed a significant difference of 11.5 letters between the treatment group and gained 2.2 letters from baseline, compared to the control group which decreased 9.3 letters*** from baseline. The difference between groups had a 95% confidence interval of 2.3 letters to 20.7 letters.
>
> More AVA-101 treated subjects improved or maintained stable vision defined as a loss of less than five letters or any letter gain with a low number of rescue treatments defined as two or fewer. Specifically, 23.8% of treated subjects maintained stable vision with no more than one rescue injection versus 9.1% in the control group. ***And a significant***

> ***number of AVA-101 treated subjects, 42.9%, improved or maintained stable vision with no more than two rescue injections as compared to 9.1% of the subjects in the control group***.
>
> ***Best corrected visual acuity improvement of 10 letters or more with no more than two rescue injections was observed in 23.8% of treated subjects and 0% of the subjects in the control group***.
>
> ***The median number of rescue injections using the protocol-specific retreatment regimen was two in AVA-101 treated subjects compared to four in the control group***. More subjects required fewer retreatments in the AVA-101 group as compared to the control group. ***Specifically, 19.0% of treated subjects received zero injections versus 9.1% in the control group. 33.3% of treated subjects received one or fewer injections versus 9.1% in the control group. And 52.4% of treated subjects received two or fewer injections versus 9.1% in the control group***.
>
> ***Retinal thickness mean change from baseline, as reported by the site using automated segmentation, was plus 25 microns for AVA-101 treated subjects compared to minus 56 microns in the control group***. The confidence interval for the difference is 17 microns to 145 microns. Further OCT analysis will be undertaken using an image reading center.

139. Despite Chalberg's attempt to put a positive spin on this data, the market was not impressed. In an article entitled "Avalanche Fails Common-Sense Test, Kicked Out of Gene Therapy Credibility Club," one commentator stated that "I'm struggling to adequately describe the awfulness of Avalanche Biotechnologies' [] performance Monday night trying to explain and defend the mediocre results of its gene therapy study in wet age-related macular degeneration (AMD)." The author pointed out that when investors looked deeper at the results, they realized the flaws, concluding that "the painful lesson here is that Avalanche's study of AVA-101 may have achieved its primary efficacy endpoint, but the gene therapy failed the more important common sense endpoint." Adam Feuerstein, *Avalanche Fails Common-Sense Test, Kicked Out of Gene Therapy Credibility Club*, The Street (June 16, 2015), http://www.thestreet.com/story/13187351/1/avalanchefailscommonsensetestkickedoutofgenetherapycredibilityclub.html. Zacks called the data "lackluster" and "weak" explaining that "results disappointed investors[.]" *Avalanche Biotechnologies Slips on Weak AVA-101 Data*, Zacks Equity Research (June 16, 2015), http://www.zacks.com/stock/news/178460/avalanche-biotechnologies-slips-on-weak-ava101-data. An article published on investing website, the Motley Fool, explained

that "[t]he problem is that the retinas of patients receiving AVA-101 thickened relative to those in the control group, casting doubt on the gene therapy's efficacy as a treatment for wet AMD[,]" "one would expect the *exact* opposite result if AVA-101 was truly helping patients maintain their visual acuity." George Budwell, *Why Avalanche Biotechnologies, Inc. Stock Collapsed Today*, Motley Fool (June 16, 2015), http://www.fool.com/investing/general/2015/06/16/why-avalanche-biotechnologies-inc-stock-collapsed.aspx.

140. Accordingly, on this news shares of Avalanche common stock dropped $21.83, or more than 56%, to close on June 16, 2015 at $17.05 per share.

141. Throughout the Class Period, Avalanche and the Individual Exchange Act Defendants represented that after announcing the data from Phase 2a of the AVA-Trial in the middle of 2015, Avalanche planned to conduct Phase 2b of the AVA-101 Trial "in the second half of 2015" which would have been "a randomized, controlled, multi-center, double-masked study to assess the efficacy, safety and tolerability of a single subretinal injection of AVA-101 in [approximately 120] subjects with wet AMD." Avalanche Biotechnologies Inc., Annual Report (Form 10-K), 18 (Mar. 5, 2015).

142. Avalanche and the Individual Exchange Act Defendants represented to investors that this plan remained intact even after the lackluster results from Phase 2a, stating during the conference call on June 15, 2015 that "we're excited and on track to start a Phase 2b study later this year." Thomas W. Chalberg, CEO, Avalanche Biotechnologies, Inc., AVA-101 Phase 2a Study Results Call, 7 (June 15, 2015) (transcript on file with Bloomberg, Inc.).

143. Anticipation for the Phase 2b study was short-lived. On August 13, 2015, after the market closed, Avalanche announced that it would not be conducting Phase 2b in the second half of 2015 or continuing its AVA-101 Trial program for Wet AMD. Specifically, in a press release issued that day, the Company stated:

> The company also reported that after further analyses of results from a previously reported Phase 2a trial of AVA-101 for the potential treatment of wet age-related macular degeneration (wet AMD), ***it will not initiate a Phase 2b clinical trial in the second half of 2015***. Instead, Avalanche will conduct additional preclinical studies to investigate optimal dose and

> delivery of AVA-101 and AVA-201 versus standard of care Anti-VEGF protein therapy to select the best gene therapy product candidate for wet AMD to advance back to the clinic.

144. In the Form 10-Q for the quarter ended June 30, 2015 ("2Q 2015 Form 10-Q"), also filed on August 13, 2015, the Company explained further, stating:

> ***Overall, we did not observe evidence of a complete and/or durable anti-VEGF response in the majority of subjects treated with AVA-101 as administered in the Phase 2a study***. We are continuing to analyze the Phase 2a data in order to enhance our understanding of the study results with respect to the secondary endpoints and why we did not see a more complete, durable anti-VEGF response. To that end, ***we have decided not to move forward with the Phase 2b clinical trial for AVA-101 with the current dose and administration procedure that we had planned to initiate in the second half of 2015. Instead, we will conduct additional preclinical studies to inform further development of our wet AMD program, which may include studies to evaluate and optimize protein expression, to compare variables impacting total anti-VEGF effect such as volume, concentration, equipment for and location of injections, as well as different routes and potential methods of administration for AVA-101*** and AVA-201, which may include both subretinal as well as intravitreal routes of administration.

145. The market reacted negatively to this news, and shares of Avalanche common stock dropped $3.82, or more than 27%, to close on August 14, 2015 at $10.01 per share.

V. ADDITIONAL SCIENTER ALLEGATIONS

146. As alleged herein, the Exchange Act Defendants acted with scienter because at the time that they issued public documents and made other public statements in Avalanche's name, they knew or recklessly disregarded the fact that such statements were materially false and misleading and/or omitted material facts concerning the interim data for the AVA-101 Trial. Exchange Act Defendants (1) knew that such documents and statements would be issued or disseminated to the investing public, (2) knew that persons were likely to rely upon those misrepresentations and omissions, and (3) knowingly and/or recklessly participated in the issuance and/or dissemination of such statements and/or documents as primary violators of the federal securities laws. The Exchange Act Defendants' materially false and misleading statements and omissions of material fact artificially inflated Avalanche's stock price during the Class Period.

147. Because the fraud alleged herein relates to the core business of Avalanche, knowledge of the facts underlying the fraudulent scheme may be imputed to the Individual Exchange Act Defendants. Indeed, Avalanche acknowledged in its 2014 Registration Statement that it has "not sold any products" and does "not expect to sell or derive revenue from any product sales for the foreseeable future" and therefore, its "business currently depends substantially on the success of AVA-101, which is still under development. If we are unable to obtain regulatory approval for, or successfully commercialize, AVA-101, our business will be materially harmed." 2014 Registration Statement at 12. Accordingly, the Individual Exchange Act Defendants, as senior level executives and/or directors at a company with only 18 full-time employees, were in such positions at the Company to access all material, non-public information concerning the interim data for the AVA-101 Trial. Thus, the Individual Exchange Act Defendants were well aware that the positive statements detailed above about the data from the AVA-101 Trial and the intention to continue with Phase 2b, made contemporaneously with knowledge of contradictory information, were materially false and/or misleading when made.

148. The Individual Exchange Act Defendants clearly had access to the Company's trial protocols and procedures as well as interim data from the AVA-101 Trial because they discussed the relevant data in detail throughout the Class Period. In addition, the Individual Exchange Act Defendants repeatedly confirmed that they received interim safety surveillance data in June 2014. Even prior to the completion of Phase 2a of the AVA-101 Trial, the Individual Exchange Act Defendants would have had access to the ongoing results given that Avalanche collaborated with the LEI in developing and conducting the trial. The Individual Exchange Act Defendants were also aware that investigators were testing visual acuity, retinal thickness, and leakage as part of the safety analysis because they participated in the design of and sought regulatory approval for the AVA-101 Trial. Finally, the members of Avalanche's Clinical Advisory Board and Scientific Advisory Board would have participated in designing the AVA-101 Trial and had access to and analyzed the data from the AVA-101 Trial.

149. Moreover, each of the Individual Exchange Act Defendants were highly educated, trained, and experienced in drug development and clinical trials and were therefore well aware that the so-called safety data necessarily included data relevant to AVA-101's efficacy. For example, Defendant Chalberg was highly educated and had extensive experience in ophthalmology research. Chalberg received an A.B. in Biochemical Sciences from Harvard University, a Ph.D. in Genetics from the Stanford University School of Medicine, and an M.B.A. from the Haas School of Business from the University of California, Berkeley. *See* 2014 Registration Statement at 103. Prior to co-finding Avalanche, Chalberg was a Howard Hughes Medical Institute Fellow at Stanford University, with research concentrations in retinal diseases and new gene therapy technologies. *See id.* Chalberg went on to work at Genentech, a publically-traded biotechnology company, holding a number of positions as Market Development Senior Manager for Lucentis and Avastin, as Group Manager for the Lucentis strategy team, and as Global Business Lead for Lucentis. *See id.* Chalberg co-founded Avalanche in 2006, had served on the Board of Directors since then, and began his tenure as the Company's President and Chief Executive Officer in October 2010. *See id.*

150. Defendant Bain is a Certified Public Accountant, who received a B.S. Accounting and Business Administration and an Honors Degree in Accounting and Business Administration from the University of the Free State in South Africa. *See id.* Prior to joining Avalanche, Bain worked at Bluebird Bio, a gene therapy biotechnology company, as a Chief Accounting Officer, Treasurer, and VP of Finance and Business Operations. *See id.* Bain has also served in positions with Genzyme, a biotechnology company, with AstraZeneca, a publicly-traded pharmaceutical company, and as VP at Fidelity Investments. *See id.* Bain joined Avalanche in April 2014, as Chief Financial Officer and Treasurer. *See id.*

151. Defendant Blumenkranz is also highly educated and has extensive experience in ophthalmology research and practice. Dr. Blumenkranz received his A.B. in Biology, his M.M.S. in Biochemical Pharmacology and his M.D. all from Brown University. *See id.* Dr. Blumenkranz then followed his medical education with a residency in ophthalmology at Stanford University. *See id.* Dr. Blumenkranz is an experienced vitreoretinal surgeon and is the current Chairman of the

Department of Ophthalmology at the Byers Eye Institute at Stanford University. *See id.* Dr. Blumenkranz also serves on a number of boards of directors for privately held biotechnology companies, including, Vantage Surgical Systems Inc., Oculogics, Inc., Presbia Holdings, Digisight Technologies Inc. and Oculeve, Inc. *See id.* Prior to co-founding Avalanche, Dr. Blumenkranz served on the faculty of the Bascom Palmer Eye Institute in Miami, Florida. *See id.* From October 1985 to August 1992, Dr. Blumenkranz founded and served as Director of the Vitreoretinal Fellowship Program at William Beaumont Hospital in Royal Oak, Michigan. *See id.* From 2000 to 2004, Dr. Blumenkranz served on the scientific advisory board of Eyetech, a biopharmaceutical company. *See id.* Dr. Blumenkranz co-founded Avalanche in 2006, and has served on its board of directors since its inception.

152. Defendant Schwartz also has experience and expertise in ophthalmology research and practice. Dr. Schwartz received his B.A. from the University of California, Berkeley, his M.D. from the Keck School of Medicine at the University of Southern California, followed by a Residency in Ophthalmology at the University of California, Los Angeles, and a vitreoretinal fellowship at Moorefield's Eye Hospital in London. *See id.* at 105. Dr. Schwartz is currently an ophthalmologist and vitreoretinal surgeon, as well as the Ahmanson Professor of Ophthalmology at the Jules Stein Eye Institute at the University of California, Los Angeles. *See id.* Prior to co-founding Avalanche, he served as the principal investigator for a number of early-stage clinical trials for retinal diseases, including studies for ranibizumab (Lucentis), as well as products in gene and cell therapy. *See id.* Dr. Schwartz also held various positions at Eyetech, a biopharmaceutical company, and currently serves on the board of directors of the American Society of Retina Specialists. *See id.* Dr. Schwartz has also served on a number of scientific advisory boards for numerous biotechnology and ophthalmology technology companies. Dr. Schwartz co-founded Avalanche in 2006, and has served on its board of directors since September 2010. *See id.*

153. According to Forms 4 filed with the SEC by Avalanche insiders, the Individual Exchange Act Defendants and certain members of the Avalanche Board of Directors took

advantage of inside information regarding known Phase 2a efficacy data, and made stock sales that were highly suspicious in both timing and amount.

154. ***Chairman of the Board of Directors Mark Blumenkranz***: Between January 13, 2015 and June 11, 2015, Blumenkranz sold thousands of shares of Avalanche common stock, as set forth in the following chart:

Trade Date	Number of Shares Sold	Sales Price	Proceeds
1/13/2015	100,000	$55.46	$5,546,000.00
4/7/2015	21,774	$38.58	$840,040.92
	726	$39.06	$28,357.56
	2,904	$38.58	$112,036.32
	96	$39.06	$3,749.76
4/8/2015	2,500	$39.93	$99,825.00
4/16/2015	24,800	$41.58	$1,031,184.00
	200	$42.04	$8,408.00
5/1/2015	20,000	$32.36	$647,200.00
5/11/2015	1,785	$34.91	$62,314.35
5/13/2015	715	$34.94	$24,982.10
5/15/2015	17,975	$35.36	$635,596.00
	4,525	$35.99	$162,854.75
5/19/2015	3,000	$36.91	$110,730.00
6/5/2015	5,000	$40.08	$200,400.00
6/9/2015	15,300	$35.52	$543,456.00
	7,000	$36.20	$253,400.00
	200	$37.35	$7,470.00
6/10/2015	600	$39.91	$23,946.00
6/11/2015	1,900	$39.97	$75,939.20

155. In a five-month span, Blumenkranz sold a total of 231,000 shares of Avalanche common stock at an average price of $38.69 per share, for total proceeds of approximately $10,417,890.[11] The proceeds amounted to approximately 243 times the annual director fees he

[11] It does not appear as though Avalanche provided a cost basis for the shares held by its executives in its SEC filings because it is an Emerging Growth Company as defined by the JOBS Act. *See* 2014 Registration Statement at 5. Accordingly, Plaintiffs have only included the insiders' proceeds from these sales.

earned during the year ended December 31, 2014.[12] Furthermore, Blumenkranz' sales during the Class Period constituted approximately 22% of his common stock holdings as of April 29, 2015.[13] Blumenkranz has not sold a single share of Avalanche common stock since the Class Period ended.

156. ***Director Steven Schwartz***: Between January 13, 2015 and June 15, 2015, Schwartz sold thousands of shares of Avalanche common stock, as set forth in the following chart:

Trade Date	Number of Shares Sold	Sales Price	Proceeds
1/13/2015	91,000	$55.46	$5,046,860.00
4/9/2015	17,050	$39.71	$677,055.50
	200	$40.37	$8,074.00
4/23/2015	16,875	$38.61	$651,543.75
5/8/2015	17,250	$33.04	$569,940.00
5/22/2015	11,679	$38.15	$445,553.85
	5,169	$38.88	$200,970.72
6/1/2015	14,157	$36.10	$511,067.70
	3,093	$36.81	$113,853.33
6/15/2015	16,875	$39.86	$ 672,637.50

157. In a five-month span, Schwartz sold a total of 193,348 shares of Avalanche common stock at an average price of $39.70 per share, for total proceeds of approximately $9,000,000. The proceeds amounted to 360 times the annual director fees he earned during the year ended December 31, 2014. Furthermore, Schwartz's sales during the Class Period constituted approximately 21% of his common stock holdings as of April 29, 2015. Schwartz has also not sold a single share of Avalanche common stock since the Class Period ended.

158. ***Former CEO Thomas W. Chalberg***: Between January 13, 2015 and June 10, 2015, Chalberg sold thousands of shares of Avalanche common stock, as set forth in the following chart:

[12] Annual director fees were derived from the "Non-Employee Director Compensation" section on page 22 of Avalanche's Schedule 14A Proxy Statement, filed with the SEC on April 30, 2015.

[13] Common stock holdings as of April 29, 2015 were derived from the "Security Ownership of Certain Beneficial Owners and Management" section on page 30 of the Avalanche Schedule 14A Proxy Statement, filed with the SEC on April 30, 2015.

Trade Date	Number of Shares Sold	Sales Price	Proceeds
1/13/2015	85,000	$55.46	$4,714,100.00
5/5/2015	25,000	$30.00	$750,000.00
6/10/2015	5,035	$36.88	$185,690.80
	12,970	$38.03	$493,249.10
	6,995	$38.90	$272,105.50

159. In a five-month span, Chalberg sold a total of 135,000 shares of Avalanche common stock at an average price of about $40 per share, for total proceeds of approximately $6,415,145. The proceeds amounted to approximately 16 times the annual salary earned in the year ended December 31, 2014. Chalberg has also not sold a single share of Avalanche common stock since the Class Period ended.

160. ***Senior VP of Business Operations Hans Hull***: Between April 7, 2015 and June 4, 2015, Hans Hull ("**Hull**") sold thousands of shares of Avalanche common stock, as set forth in the following chart:

Trade Date	Number of Shares Sold	Sales Price	Proceeds
4/7/2015	26,613	$38.58	$1,026,729.54
	887	$35.44	$31,438.24
5/4/2015	5,000	$30.87	$154,350.00
6/4/2015	2,000	$37.64	$75,283.20

161. In a short two-month span, Hull sold a total of 34,500 shares of Avalanche common stock at an average price of $35.63 per share, for total proceeds of approximately $1,287,801. The proceeds amounted to approximately 5 times the annual salary he earned during the year ended December 31, 2014.[14] Furthermore, Hull's sales during the Class Period constituted approximately 57% of his common stock holdings as of April 29, 2015. Hull has not sold a single share of Avalanche common stock since the Class Period ended.

[14] Annual salary was derived from the "Executive and Director Compensation" section on page 112 of Avalanche's Form S-1 Registration Statement, filed with the SEC on January 1, 2015.

162. ***Director Paul Wachter***: Between January 13, 2015 and June 15, 2015, Wachter sold thousands of shares of Avalanche common stock, as set forth in the following chart:

Trade Date	Number of Shares Sold	Sale Price	Proceeds
1/13/2015	14,000	$55.46	$776,440.00
4/13/2015	830	$39.09	$32,444.70
	338	$39.84	$13,465.92
	24	$40.74	$977.76
4/20/2015	1,192	$40.19	$47,906.48
4/27/2015	1,192	$35.60	$42,435.20
5/4/2015	1,192	$30.86	$36,785.12
5/11/2015	508	$32.79	$16,657.32
	552	$33.70	$18,602.40
	132	$34.29	$4,526.28
5/18/2015	1,192	$35.30	$42,077.60
5/26/2015	786	$36.51	$28,696.86
	304	$37.59	$11,427.36
	102	$38.29	$3,905.58
6/1/2015	982	$36.11	$35,460.02
	210	$36.81	$7,730.10
6/8/2015	541	$37.96	$20,536.36
	475	$38.95	$18,501.25
	176	$39.88	$7,018.88
6/15/2015	1,192	$39.86	$47,513.12

163. In a five-month span, Wachter sold a total of 25,920 shares of Avalanche common stock at an average price of approximately $38 per share, for total proceeds of approximately $1,213,108. The proceeds amounted to approximately 58 times the annual director fees he earned during the year ended December 31, 2014. Furthermore, Wachter's sales during the Class Period constituted approximately 36% of his common stock holdings as of April 29, 2015. Wachter has not sold a single share of Avalanche common stock since the Class Period ended.

164. ***Senior VP of Pharmaceutical Development Mehdi Gasmi***: Between April 7, 2015 and June 15, 2015, Medhi Gasmi ("**Gasmi**") sold thousands of shares of Avalanche common stock, as set forth in the following chart:

Trade Date	Number of Shares Sold	Sale Price	Proceeds
4/7/2015	8,708	$38.58	$335,954.64
	292	$39.06	$11,405.52
4/14/2015	1,000	$39.44	$39,440.00
4/21/2015	1,000	$39.21	$39,210.00
4/28/2015	1,000	$35.67	$35,667.00
5/7/2015	500	$33.27	$16,635.00
5/14/2015	500	$35.31	$17,655.00
5/21/2015	500	$38.87	$19,435.00
5/28/2015	500	$38.01	$19,005.00
6/8/2015	235	$37.96	$8,920.60
	183	$38.95	$7,127.85
	82	$39.88	$3,270.16
6/15/2015	500	$39.86	$19,930.00

165. In a short two-month span, Gasmi sold a total of 15,000 shares of Avalanche common stock at an average price of approximately $38 per share, for total proceeds of approximately $573,659. The proceeds amounted to approximately twice his annual salary during the year ended December 31, 2014. Furthermore, Gasmi's sales during the Class Period constituted approximately 48% of his common stock holdings as of April 29, 2015. Gasmi has not sold a single share of Avalanche common stock since the Class Period ended.

166. ***Former CFO Linda Bain***: Between May 4, 2015 and June 12, 2015, Bain sold thousands of shares of Avalanche common stock as set forth in the following chart:

Trade Date	Number of Shares Sold	Sale Price	Proceeds
5/4/2015	2,500	$31.58	$78,950.00
5/11/2015	715	$34.91	$24,960.65
5/13/2015	285	$34.94	$9,957.90
6/12/2015	3,500	$39.94	$139,790.00

167. In a very brief one-month span, Bain sold a total of 7,000 shares of Avalanche common stock at an average price of $35.34 per share, for total proceeds of approximately

$253,659. Bain has not sold a single share of Avalanche common stock since the Class Period ended.

168. While Avalanche and the Individual Exchange Act Defendants repeatedly insisted to the public that the only Phase 2a data they had received was interim drug "safety" data in June 2014, the Individual Exchange Act Defendants along with the other Avalanche executive listed above, sold a combined total of 641,768 shares of Avalanche common stock, for combined proceeds of over $29,161,262—more than 25% of the proceeds Avalanche obtained in the IPO—in a span of only five months, with the heaviest trading (55% of shares sold) occurring 70 days prior to the release of the Phase 2a efficacy results. Furthermore, the average percentage of holdings sold during the five month period, across the Individual Exchange Act Defendants and Avalanche executives listed above, was approximately 29%.

169. The timing of the above-mentioned insider sales creates a strong inference of scienter. Most of the sale dates (97%) fall in the 70 day window leading up to the Company's Phase 2a results announcement, with almost every insider noted above selling a few days before the Company announced its Phase 2a results.

170. Many of the insiders' sales noted above occurred successively—often within days of their prior sales—and occurred in a short window of time. Some of the insiders' sales occurred on overlapping dates. For example, on April 7, 2015, Blumenkranz, Hull, and Gasmi all sold shares, while on May 4, 2015, Hull, Wachter and Bain all sold shares. Furthermore, as indicated above, none of the insiders sold shares after the announcement of the disappointing Phase 2a data.

171. Most of the insiders noted above sold at an average sale price of approximately $38-$40 per share, only a few dollars under the peak price of approximately $42 per share both in mid-April and mid-June, after the trading lock-up period came to a close in early April 2015.

172. Furthermore, Blumenkranz, Chalberg, Schwartz, and Wachter all took advantage of the one exception in the lock-up period imposed by the IPO and sold thousands of shares in the 2015 Offering. Also, the 2015 Offering imposed an additional lock-up period of 90 days following. Accordingly, when the lock-up periods finally came to a close on April 7, 2015, the Avalanche

insiders soon after began an onslaught of trades, with a number of insiders trading that same day and almost every insider selling a significant number of shares in April 2015.

173. Also supporting an inference of scienter, Chalberg resigned on July 23, 2015, shortly after the topline results from Phase 2a were released; and Bain resigned on October 19, 2015, shortly after the Company decided not to continue with a Phase 2b trial.

VI. LOSS CAUSATION

174. During the Class Period, as detailed herein, the Exchange Act Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated Avalanche's stock price and operated as a fraud or deceit on Class Period purchasers of Avalanche stock by misrepresenting the Company's business and prospects. During the Class Period, the Exchange Act Defendants misrepresented and concealed the negative efficacy data from the AVA-101 Trial. As a result of their purchases of Avalanche stock during the Class Period at artificially inflated prices, Plaintiffs and other Class members suffered damages as the true facts and Avalanche's fraud were revealed.

175. The Exchange Act Defendants' wrongful conduct, as alleged herein, directly and proximately caused the damages suffered by Plaintiffs and the Class.

176. The Exchange Act Defendants' false and misleading statements and omissions in their SEC filings and other public statements during the Class Period directly caused losses to Plaintiffs and the Class. On the strength of these false statements, the Company's stock price was artificially inflated to a Class Period high of $60.08 per share on January 7, 2015. Those misrepresentations and omissions that were not immediately followed by an upward movement in the Company's stock price served to maintain the share price at artificially inflated levels by maintaining and supporting a false positive perception of Avalanche's business, operations, performance, and prospects.

177. As the truth began to emerge regarding the adverse patient data from AVA-101, the price of Avalanche's stock declined as the market processed each set of previously undisclosed facts. Each such disclosure removed a portion of the artificial inflation in the price of Avalanche's

common stock and directly and proximately caused Plaintiffs and other Class members to suffer damages. For example, on January 16, 2015, shares of Avalanche common stock closed at $48.37, down 6% from the day prior. On June 16, 2015, shares of Avalanche common stock closed at $17.05 per share, a 56% decline on unusually heavy volume.

178. Until shortly before Plaintiffs filed this Complaint, they were unaware of the facts alleged herein and could not have reasonably discovered the Exchange Act Defendants' misrepresentations and omissions by the exercise of reasonable diligence.

VII. CONTROL PERSON LIABILITY

179. The Individual Exchange Act Defendants are liable as direct participants with respect to the wrongs complained of herein. In addition, the Individual Exchange Act Defendants, by reason of their status as senior executive officers and/or directors, were "controlling persons" within the meaning of Section 20(a) of the Exchange Act, and each had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Exchange Act Defendants were able to and did, directly or indirectly, control the conduct of Avalanche's business.

180. Specifically, because of their positions within the Company, the Individual Exchange Act Defendants possessed the power and authority to control the contents of Avalanche's SEC filings, annual and quarterly reports, press releases, and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market, including those containing the materially false and misleading statements and omissions of material fact alleged herein. Each of the Individual Exchange Act Defendants, by reason of his/her respective management or board position, had the ability and opportunity to review copies of the Company's SEC filings, reports, press releases, and other statements alleged herein to be misleading, prior to, or shortly after their issuance or to cause them to be corrected.

181. By virtue of their positions, the Individual Exchange Act Defendants had access to material non-public information. Each of the Individual Exchange Act Defendants knew or recklessly disregarded the fact that the adverse facts specified herein had not been disclosed and

were being concealed from the public, and that the positive representations which were being made were then materially false and misleading.

VIII. APPLICABILITY OF THE FRAUD ON THE MARKET DOCTRINE

182. The market for Avalanche's common stock was an efficient market for the following reasons, among others:

a) Avalanche's common stock was listed and actively traded on the NASDAQ GM, a highly efficient national market;

b) As a registered and regulated issuer of securities, Avalanche filed periodic reports with the SEC, in addition to the frequent voluntary dissemination of information;

c) Avalanche regularly communicated with public investors through established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures such as communications with the financial press and other similar reporting services;

d) Avalanche was followed by multiple analysts, which followed Avalanche's business and wrote reports which were publicly available and affected the public marketplace;

e) The material misrepresentations and omissions alleged herein would tend to induce a reasonable investor to misjudge the value of Avalanche's stock; and

f) Without knowledge of the misrepresented or omitted facts, Plaintiffs and other members of the Class purchased Avalanche stock between the time the Exchange Act Defendants made the material misrepresentations and omissions and the time that the truth was revealed, during which time the price of Avalanche stock was artificially inflated by the Exchange Act Defendants' misrepresentations and omissions.

183. As a result of the above, the market for Avalanche securities promptly digested current information with respect to the Company from all publicly available sources and reflected such information in the security's price. The historical daily trading prices and volumes of Avalanche's publicly traded stock are incorporated by reference herein. Under these circumstances, many purchasers of Avalanche common stock during the Class Period suffered similar injuries through their purchases of shares at prices which were artificially inflated by the Exchange Act Defendants' misrepresentations and omissions. Thus, a presumption of reliance applies.

IX. APPLICABILITY OF FRAUD ON THE REGULATORY PROCESS DOCTRINE

184. Plaintiffs are entitled to a presumption of reliance based on the fraud on the regulatory process doctrine, because they reasonably relied on the integrity of the regulatory system. The fraud on the regulatory process presumption of reliance was established by the 9th Circuit in *Arthur Young and Co. v. United States District Ct.*, 549 F. 2d 686 (9th Cir. 1976), cert. denied, 434 U.S. 829 (1977).

185. In the 2014 Registration Statement, the Exchange Act Defendants failed to disclose material facts to the SEC and NASDAQ, in applying for and obtaining permission to sell Avalanche common stock publicly in an IPO and having those securities listed for trading on NASDAQ. Namely, the Exchange Act Defendants failed to disclose material facts regarding adverse patient data. Had they disclosed this information, Avalanche would not have been able to list its securities on the NASDAQ market, sell its securities publicly to investors and complete the IPO. Furthermore, Plaintiffs and Class members relied on the regulatory process, as preparation of the 2014 Registration Statement depended on the due diligence of the Underwriter Defendants.

186. When purchasing Avalanche common stock, Plaintiffs and Class members reasonably relied on the availability of those securities as an indication of their genuineness and legality. The Exchange Act Defendants' omissions were therefore a fraud on the regulatory process, permitting Class members a presumption of reliance.

X. THE AFFILIATED UTE PRESUMPTION

187. Plaintiffs are entitled to a presumption of reliance under *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the claims asserted herein against the Exchange Act Defendants are predicated primarily on omissions of material fact which the Exchange Act Defendants had a duty to disclose. Under *Affiliated Ute*, all that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making a decision to purchase or sell the securities. *Id.* at 153-54. Here, the Exchange Act Defendants had a duty but failed to disclose, at the time of issuance, material facts regarding poor Phase 2a efficacy data. These facts would have been important to a reasonable investor, as part of Avalanche's success depends on the outcome of its clinical trials.

XI. NO SAFE HARBOR

188. The safe harbor provisions for forward-looking statements under the Private Securities Litigation Reform Act of 1995 are applicable only under certain circumstances that do not apply to any of the materially false and misleading statements and omissions alleged in this Complaint.

189. First, many of the identified false and misleading statements and omissions herein are not forward-looking statements, but instead are statements of current or historic fact.

190. Second, to the extent there were any forward-looking statements that were identified as such at the time made, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

191. Third, such false and misleading statements were not accompanied by cautionary language that was meaningful because any such warnings or "risk" factors contained in, or incorporated by reference in, the relevant press release, SEC filings, earnings class, or other public statements described herein were general, "boilerplate" statements of risk that would affect any pharmaceutical development company, and misleadingly contained no factual disclosure of any of

the specific details of the endemic problems affecting the Company during the Class Period, or similar important factors that would give investors adequate notice of such risks.

192. Fourth, to the extent there were any forward-looking statements that were identified as such at the time made, the Exchange Act Defendants are liable for those false and misleading forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, or, by reason of what the speaker failed to note, was materially false and/or misleading, and/or that each such statement was authorized and/or approved by a director and/or executive officer of Avalanche who actually knew that each such statement was false or misleading when made.

XII. CLAIMS FOR RELIEF UNDER THE EXCHANGE ACT

COUNT I

For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against The Exchange Act Defendants

193. Plaintiffs re-allege each allegation above as if fully set forth herein.

194. This claim is brought under Section 10(b) of the Exchange Act (15 U.S.C. § 78j(b)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5), against the Exchange Act Defendants.

195. During the Class Period, the Exchange Act Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(b) promulgated thereunder by making the false and misleading statements specified herein, including the statements in SEC filings, presentations, press releases, and analyst reports concerning the data for the AVA-101 Trial reviewed by the Exchange Act Defendants, whose truth they knowingly or recklessly disregarded when they failed to disclose material facts necessary to make the statements made, in light of the circumstances under which they were made, not false and misleading.

196. During the Class Period, the Exchange Act Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(a) & (c) promulgated thereunder by employing devices, schemes, and artifices to defraud and engaging in acts, practices, and a course of conduct that operated as a

fraud or deceit upon Plaintiffs and other members of the Class in that the Exchange Act Defendants concealed the adverse patient data from the investing public.

197. The Exchange Act Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or the mails, engaged and participated in a continuous course of conduct to conceal non-public, adverse material information about the Company's operations and financial condition as reflected in the misrepresentations and omissions set forth above.

198. The Exchange Act Defendants each had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth by failing to ascertain and to disclose such facts even though such facts were available to them, or deliberately refrained from taking steps necessary to discover whether the material facts were false or misleading.

199. As a result of the Exchange Act Defendants' dissemination of materially false and misleading information and their failure to disclose material facts, Plaintiffs and the Class Members were misled into believing that the Company's statements and other disclosures were true, accurate, and complete.

200. Avalanche is liable for the acts of the Individual Exchange Act Defendants and other Company personnel referenced herein under the doctrine of respondeat superior, as those persons were acting as the officers, directors, and/or agents of Avalanche in taking the actions alleged herein.

201. Plaintiffs and Class members purchased Avalanche common stock, without knowing that the Exchange Act Defendants had misstated or omitted material facts about the Company's operations and financial performance or prospects. In so doing, Plaintiffs and Class members relied directly or indirectly on false and misleading statements made by the Exchange Act Defendants, and/or an absence of material adverse information that was known to Defendants or recklessly disregarded by them but not disclosed in the Exchange Act Defendants' public statements.

Plaintiffs and Class members were damaged as a result of their reliance on the Exchange Act Defendants' false statements and misrepresentations and omissions of material facts.

202. At the time of the Exchange Act Defendants' false statements, misrepresentations and omissions, Plaintiffs and Class members were unaware of their falsity and believed them to be true. Plaintiffs and the Class would not otherwise have purchased Avalanche common stock had they known the truth about the matters discussed above.

203. Plaintiffs are filing this action within two years after discovery of the facts constituting the violation, including facts establishing scienter and other elements of Plaintiffs' claims, and within five years after the violations with respect to Plaintiffs' investments.

204. By virtue of the foregoing, the Exchange Act Defendants have violated § 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

205. As a direct and proximate result of the Exchange Act Defendants' wrongful conduct, Plaintiffs and the Class have suffered damages in connection with their purchase of Avalanche common stock.

COUNT II

For Violations of Section 20(a) of the Exchange Act Against the Individual Exchange Act Defendants

206. Plaintiffs reallege each allegation above as if fully set forth herein.

207. This Count is asserted against the Individual Exchange Act Defendants for violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), on behalf of all members of the Class.

208. As set forth above, Avalanche committed a primary violation of Section 10(b) of the Exchange Act by knowingly and/or recklessly disseminating materially false and misleading statements and/or omissions throughout the Class Period as well as by participating in a scheme to conceal the adverse patient data from the investing public.

209. Each of the Individual Exchange Act Defendants, by reason of their status as senior executive officers and/or directors of Avalanche, directly or indirectly, controlled the conduct of the Company's business and its representations to Plaintiffs and the Class, within the meaning of

§20(a) of the Exchange Act. The Individual Exchange Act Defendants directly or indirectly controlled the content of the Company's SEC statements and press releases related to Plaintiffs' and the Class' investments in Avalanche common stock within the meaning of §20(a) of the Exchange Act. Therefore, the Individual Exchange Act Defendants are jointly and severally liable for the Company's fraud, as alleged herein.

210. The Individual Exchange Act Defendants controlled and had the authority to control the content of the Company's SEC statements and press releases. Because of their close involvement in the every-day activities of the Company, and because of their wide-ranging supervisory authority, the Individual Exchange Act Defendants reviewed or had the opportunity to review these documents prior to their issuance, or could have prevented their issuance or caused them to be corrected.

211. The Individual Exchange Act Defendants knew or recklessly disregarded the fact that Avalanche's representations were materially false and misleading and/or omitted material facts when made. In so doing, the Individual Exchange Act Defendants did not act in good faith.

212. By virtue of their high-level positions and their participation in and awareness of Avalanche's operations and public statements, the Individual Exchange Act Defendants were able to and did influence and control Avalanche's decision-making, including controlling the content and dissemination of the documents that Plaintiffs and the Class contend contained materially false and misleading information and on which Plaintiffs and the Class relied.

213. The Individual Exchange Act Defendants had the power to control or influence the statements made giving rise to the securities violations alleged herein, and as set forth more fully above.

214. As set forth above, Avalanche committed a primary violation of Section 10(b) of the Exchange Act by knowingly and/or recklessly disseminating materially false and misleading statements and/or omissions throughout the Class Period as well as by participating in a scheme to conceal the adverse patient data from the investing public.

215. As a direct and proximate result of the Individual Exchange Act Defendants' wrongful conduct, Plaintiffs and the Class suffered damages in connection with their purchase of Avalanche common stock.

SECURITIES ACT CLAIMS

216. In this part of the Complaint, separate and apart from the claims set forth above under the Exchange Act, Plaintiff asserts, on behalf of the Class, strict liability claims under Section 11 and 15 of the Securities Act. These claims are based on allegedly untrue statements and omissions made in the 2014 Registration Statement filed in connection with Avalanche's IPO. Plaintiff expressly disclaims any allegations of fraud for these Securities Act claims.

217. This action was brought within one year after the discovery of the untrue statements and omissions (and within one year after such discovery should have been made in the exercise of reasonable diligence) and within three years after the IPO.

218. The Securities Act Plaintiff asserts Section 11 and 15 claims against the defendants specified below, on behalf of all persons and entities, other than the defendants and certain related parties, who purchased shares of Avalanche common stock pursuant or traceable to the 2014 Registration Statement in connection with Avalanche's IPO and suffered damages thereby.

XIII. SECURITIES ACT PARTIES

A. The Securities Act Plaintiff

219. Plaintiff Srikanth Koneru, purchased 71 shares of Avalanche common stock at $25.81 on July 31, 2014 and was damaged thereby. Plaintiff still holds all of his shares as of the date of the filing of this Complaint.

B. The Securities Act Defendants

220. Defendant Avalanche is a Delaware corporation with its principal executive offices located at 1035 O'Brien Drive, Suite A, Menlo Park, California 94025. Avalanche is a biopharmaceutical company that uses its proprietary Ocular BioFactory™ platform to discover and develop novel treatments for ophthalmic diseases. During the Class Period, the Company's stock was traded on the NASDAQ Global Select Market ("**NASDAQ**") under the symbol "AAVL."

1. The Individual Securities Act Defendants

221. Defendant Chalberg was the co-founder of Avalanche, and was until his resignation on July 23, 2015, CEO, president, and member of the Board of Directors of Avalanche. Chalberg signed the 2014 Registration Statement in connection with the IPO.

222. Defendant Bain was, at all relevant times, the CFO of Avalanche. Defendant Bain signed the 2014 Registration Statement in connection with the IPO.

223. Defendant Blumenkranz was at all relevant times the Chairman of the Board of Directors of Avalanche. Defendant Blumenkranz signed the 2014 Registration Statement in connection with the IPO.

224. Defendant Schwartz was at all relevant times a member of Avalanche's Board of Directors. Defendant Schwartz signed the 2014 Registration Statement in connection with the IPO.

225. Defendant McLaughlin was at all relevant times a member of Avalanche's Board of Directors. Defendant McLaughlin signed the 2014 Registration Statement in connection with the IPO. McLaughlin directly participated in and controlled management of the Company, including, without limitation, the publication of statements by and on behalf of Avalanche concerning AVA-101 in the Company's press releases, SEC filings, and other public statements.

226. Defendant Wachter was at all relevant times a member of Avalanche's Board of Directors. Defendant Wachter signed the 2014 Registration Statement in connection with the IPO. Wachter directly participated in and controlled management of the Company, including, without limitation, the publication of statements by and on behalf of Avalanche concerning AVA-101 in the Company's press releases, SEC filings, and other public statements.

227. The defendants listed in ¶¶221-227 are collectively referred to herein as the "**Individual Securities Act Defendants**."

2. The Underwriter Defendants

228. Defendant Jefferies acted as an underwriter of the IPO. Jefferies is headquartered at 520 Madison Avenue, 10th Floor, New York, NY 10022.

229. Defendant Cowen acted as an underwriter of the IPO. Cowen is headquartered at 599 Lexington Avenue, New York, NY 10022.

230. Defendant Piper Jaffray acted as an underwriter of the IPO. Piper Jaffray is headquartered at 800 Nicollet Mall, Suite 1000, Minneapolis, MN 55402.

231. Defendant William Blair acted as an underwriter of the IPO. William Blair is headquartered at 222 West Adams Street, Chicago, IL 60606.

232. The defendants enumerated in ¶¶228-232 are collectively referred to herein as the "**Underwriter Defendants**."

233. The Company, the Individual Securities Act Defendants, and the Underwriter Defendants are collectively referred to herein under the Securities Act Claims section as the "**Securities Act Defendants**."

234. Pursuant to the Securities Act, the Underwriter Defendants are liable for the false and misleading statements in the 2014 Registration Statement. Representatives of the Underwriter Defendants assisted Avalanche and the Individual Securities Act Defendants in planning the IPO and purportedly conducted an adequate and reasonable due diligence investigation into the business and operations of Avalanche. As part of their due diligence investigation the Underwriter Defendants had continuous access to confidential corporate information concerning Avalanche's clinical trials as well as met with Avalanche's lawyers, management, and top executives. As a result, a reasonable due diligence investigation would have revealed the misleading statements and omissions contained in the 2014 Registration Statement, as detailed herein.

235. The Underwriter Defendants caused the 2014 Registration Statement to be filed with the SEC and declared effective with connection with offers and sales thereof, including to Plaintiff and the Class.

XIV. BACKGROUND OF THE SECURITIES ACT CLAIMS

236. In connection with the 2014 Registration Statement for the IPO, the Securities Act Defendants negligently made untrue statements and omitted material facts regarding the data

received and reviewed by Avalanche and management prior to the June 15, 2015 top-line results were announced, as set forth in Section II above.

XV. CLASS PERIOD STATEMENTS

237. On or about May 30, 2014, Avalanche filed with the SEC its registration statement on Form S-1 (Registration No 333-197133). Following amendment, on July 30, 2014 the registration statement was declared effective by the SEC and the Securities Act Defendants priced the IPO at $17 per share. On July 31, 2014, the first day of the Class Period, Avalanche and the Individual Securities Act Defendants filed the 2014 Prospectus, which forms part of the 2014 Registration Statement (the 2014 Prospectus was incorporated into the registration statement and together they formed what is referred to herein as the "2014 Registration Statement") with the SEC, and sold 6,900,000 shares of common stock to the investing public for total proceeds of $106.8 million, after deducting underwriting discounts, commissions, and expenses. All of the Individual Securities Act Defendants signed the 2014 Registration Statement. The 2014 Offering was completed on August 5, 2014.

238. As described below, the 2014 Registration Statement contained untrue statements of material facts or omitted to state other facts necessary to make the statements made not misleading, and was not prepared in accordance with the rules and regulations regarding is preparation.

239. There were two general categories of misstatements and omissions: (1) statements and omissions concerning the data from the AVA-101 Trial viewed by the Company and Avalanche management prior to the IPO; and (2) statements and omissions regarding the risks facing the Company arising from the efficacy, or lack thereof, of AVA-10l.

240. For example, in regard to the data viewed by the Company and Avalanche management prior to the IPO, Avalanche and the Individual Securities Act Defendants stated in the 2014 Registration Statement:

> We are currently conducting a Phase 2a trial for AVA-101 at LEI with 32 additional wet AMD subjects. ***Interim drug safety surveillance data received in June 2014 from this ongoing study suggests that AVA-101 continues to be well tolerated***. Most adverse events that have been observed to date are mild and not related to AVA-101 or the procedures

> used in the study. Adverse events related to study procedures include subconjunctival, vitreous and retinal hemorrhage, cataract progression and eye pain. Other infrequent adverse events may be related to study procedures, including retinal tears or holes and falls. A small number of adverse events may be possibly related to AVA-101, including inflammation and light chain analysis increase, but these were considered mild and transient and have not been associated with vision loss. We expect to receive top-line data from this ongoing Phase 2a trial in mid-2015.
>
> * * *
>
> We are currently conducting a Phase 2a trial for AVA-101 in wet AMD. ***Interim drug safety surveillance data received in June 2014 from this ongoing study suggests that AVA-101 continues to be well tolerated. We expect to receive top-line data from this ongoing Phase 2a trial in mid-2015.***

241. In regard to the risks facing the Company at the time of the offering, Avalanche and the Individual Securities Act Defendants stated in the 2014 Registration Statement:

> ***Our business currently depends substantially on the success of AVA-101, which is still under development. If we are unable to obtain regulatory approval for, or successfully commercialize, AVA-101, our business will be materially harmed.***
>
> * * *
>
> ***Successful continued development and ultimate regulatory approval of AVA-101 is critical for our future business success***. . . .
>
> ***The future regulatory and commercial success of this product candidate is subject to a number of risks, including the following:***
>
> > ***we may not be able to provide evidence of efficacy and safety for AVA-101***;
> >
> > ***the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory bodies for marketing approval;***
>
> * * *
>
> ***Our ability to commercialize our product candidates effectively will depend on several factors, including the following:***
>
> > ***successful completion of preclinical studies and clinical trials, including the ability to demonstrate safety and efficacy of our product candidates***
>
> * * *

[S]uccess in early clinical trials does not mean that later clinical trials will be successful, because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing.

* * *

If our proprietary vectors are not shown to be safe and effective in targeting retinal tissue, we may not realize the value of our investment in directed evolution technology.

* * *

In addition, ***success in early clinical trials does not mean that later clinical trials will be successful, because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. . . .***

We cannot be certain that any of our planned clinical trials will be successful, ***and any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.***

* * *

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

> ***we or any of our future development partners may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe and effective for any indication***;
>
> ***the results of clinical trials may not demonstrate the safety or efficacy required*** by such authorities for approval;

* * *

The degree of market acceptance of our product candidates will depend on a number of factors, including:

> ***demonstration of clinical efficacy and safety compared to other more-established products;***

* * *

Reimbursement by a third-party payer may depend upon a number of factors including the third-party payer's determination that use of a product candidate is:

> ***safe, effective and medically necessary***;

* * *

All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities.

242. The foregoing statements in ¶¶240-241were materially false and/or misleading because they omitted and/or misrepresented the following adverse facts that existed:

a) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were experiencing significant thickening of the retina, evidencing that AVA-101 was not effective in treating Wet AMD;

b) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were requiring multiple rescue injections, evidencing that AVA-101 was not effective in treating Wet AMD;

c) As explained in ¶¶45-55, 58-60, 70, 74, 78, 80-82, 84, and 86, patients in Phase 2a of the AVA-101 Trial were not experiencing significant improvements in visual acuity scores required to justify the increased risk of adverse safety events, evidencing that AVA-101 was not effective in treating Wet AMD; and

d) As a result, Avalanche's business and financial prospects concerning AVA-101 were not what the speakers had led the market to believe they were.

243. In addition to the foregoing omissions, the 2014 Registration Statement failed to disclose "any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations" as required by Item 303(a) of Regulation S-K. 17 C.F.R. § 229.303(a). The 2014 Registration Statement was required to disclose the uncertainties created by the adverse patient data from the AVA-101 Trial viewed in June 2014. The Offering Documents, however, omitted this information.

244. Under Item 503 of Regulation S-K, an issuer must include in its registration statement "the most significant factors that make the offering speculative or risky" and must "[e]xplain how the risk affects the issuer or the securities being offered." 17 C.F.R. §229.503.

Thus, the 2014 Registration was required to include a discussion of the most significant risk facing Avalanche—that Avalanche was already in possession of adverse patient data from Phase 2a of the AVA-101 Trial that showed (a) patients in Phase 2a of the AVA-101 Trial were experiencing significant thickening of the retina, evidencing that AVA-101 was not effective in treating Wet AMD; (b) patients in Phase 2a of the AVA-101 Trial were requiring multiple rescue injections, evidencing that AVA-101 was not effective in treating Wet AMD; (c) patients in Phase 2a of the AVA-101 Trial were not experiencing significant improvements in visual acuity scores required to justify the increased risk of adverse safety events, evidencing that AVA-101 was not effective in treating Wet AMD.

245. The 2014 Registration Statement also violated Item 408 of Regulation C. Item 408 imposes a duty to disclose material information necessary to ensure that representations in a registration statement are not misleading by requiring that, "[i]n addition to the information expressly required to be included in a registration statement, there shall be added such further material information, if any, as may be necessary to make the required statements, in light of the circumstances under which they are made, not misleading." 17 C.F.R. § 230.408(a). The 2014 Registration Statement contained material omissions of information that were required to be disclosed to make the statements in the 2014 Registration Statement not misleading. Specifically, the statements in ¶¶237-241 were misleading in light of the Securities Act Defendants' failure to disclose that the adverse patient data reviewed in June 2014 also revealed that AVA-101 was not effective, *i.e.*, it was not inducing an anti-VEGF response in subjects.

246. Finally, because Avalanche was conducting a public offering of common stock, it was required to disclose all material inside information.

247. On July 30, 2014, Avalanche priced its IPO at $17.00 per share. Avalanche's stock price closed at $27.99 on the day of the IPO, climbing nearly 40% in one day, even after being priced above expectations.

248. After the market closed on June 15, 2015, Avalanche announced the top-line results from Phase 2a of its AVA-101 Trial. In regard to the primary endpoint, safety, the Company

explained that Avalanche's "Phase 2a clinical study for AVA-101 met its 12-month primary endpoint, based on ophthalmic and systemic safety, demonstrating that AVA-101 was well tolerated with a favorable safety profile in subjects with wet age-related macular degeneration[.]" In regard to the secondary endpoints for Phase 2a, the Company stated the following:

> ***Overall, BCVA mean change from baseline did show a significant difference of 11.5 letters between the treatment (+2.2 letters) and control (-9.3 letters) groups (95 percent CI, 2.3-20.7 letters)***.
>
> More AVA-101 treated subjects improved or maintained stable vision (>-5 letters) with a low number (≤2) of rescue treatments. Specifically, 23.8 percent (treated) vs. 9.1 percent (control) maintained stable vision with ≤1 rescue injections, and a significant number of AVA-101 treated subjects (42.9 percent) improved or maintained stable vision with ≤2 rescue injections compared with subjects in the control group (9.1 percent).
>
> BCVA improvement of ≥10 letters with ≤2 rescue injections was observed in 23.8 percent of treated subjects and 0 percent of subjects in the control group.
>
> ***The median number of rescue injections using the protocol-specified retreatment regimen was 2 (95 percent CI, 1-6 injections) in AVA-101 treated subjects compared with 4 (95 percent CI, 3-5 injections) in the control group***. More subjects required fewer retreatments in the treatment group compared with control (19.0 percent vs. 9.1 percent with 0 injections; 33.3 percent vs. 9.1 percent with ≤1 injections; 52.4 percent vs. 9.1 percent with ≤2 injections).
>
> ***Retinal thickness mean change from baseline***, as reported by the site using automated segmentation, ***was +25 µm for AVA-101 treated subjects compared with -56 µm in the control group*** (CI for the difference, 17 to 145 µm). Additional evaluation of SD-OCT images by an image reading center are ongoing.

249. Later that day the Company held a special conference call to discuss the top-line data and further reiterated several times that "the key takeaway is that this was a positive Phase 2a study that met its primary objective which was to further establish safety of AVA-101 in wet AMD patients and also help inform future studies going forward . . . we're very encouraged to also see that AVA-101 showed promising signs of efficacy[.]" The Company, Barone, and Chalberg also provided more detail regarding the AVA-101 Trial results, stating the following:

> [Barone]: The primary endpoint was safety and tolerability of AVA-101 as measured by ophthalmic and/or systemic complications and laboratory tests. . . . The study met its primary endpoint. . . .

> [D]ata from secondary endpoints suggest evidence of biological activity in subjects treated with AVA-101. ***Overall, mean change in best corrected visual acuity from baseline showed a significant difference of 11.5 letters between the treatment group and gained 2.2 letters from baseline, compared to the control group which decreased 9.3 letters*** from baseline. The difference between groups had a 95% confidence interval of 2.3 letters to 20.7 letters.
>
> More AVA-101 treated subjects improved or maintained stable vision defined as a loss of less than five letters or any letter gain with a low number of rescue treatments defined as two or fewer. Specifically, 23.8% of treated subjects maintained stable vision with no more than one rescue injection versus 9.1% in the control group. ***And a significant number of AVA-101 treated subjects, 42.9%, improved or maintained stable vision with no more than two rescue injections as compared to 9.1% of the subjects in the control group***.
>
> ***Best corrected visual acuity improvement of 10 letters or more with no more than two rescue injections was observed in 23.8% of treated subjects and 0% of the subjects in the control group***.
>
> ***The median number of rescue injections using the protocol-specific retreatment regimen was two in AVA-101 treated subjects compared to four in the control group***. More subjects required fewer retreatments in the AVA-101 group as compared to the control group. ***Specifically, 19.0% of treated subjects received zero injections versus 9.1% in the control group. 33.3% of treated subjects received one or fewer injections versus 9.1% in the control group. And 52.4% of treated subjects received two or fewer injections versus 9.1% in the control group***.
>
> ***Retinal thickness mean change from baseline, as reported by the site using automated segmentation, was plus 25 microns for AVA-101 treated subjects compared to minus 56 microns in the control group***. The confidence interval for the difference is 17 microns to 145 microns. Further OCT analysis will be undertaken using an image reading center.

250. Despite Chalberg's attempt to put a positive spin on this data, the market was not impressed. In an article entitled "Avalanche Fails Common-Sense Test, Kicked Out of Gene Therapy Credibility Club," one commentator stated that "I'm struggling to adequately describe the awfulness of Avalanche Biotechnologies' [] performance Monday night trying to explain and defend the mediocre results of its gene therapy study in wet age-related macular degeneration (AMD)." The author pointed out that when investors looked deeper at the results, they realized the flaws, concluding that "the painful lesson here is that Avalanche's study of AVA-101 may have achieved its primary efficacy endpoint, but the gene therapy failed the more important common

sense endpoint." Adam Feuerstein, *Avalanche Fails Common-Sense Test, Kicked Out of Gene Therapy Credibility Club*, The Street (June 16, 2015), http://www.thestreet.com/story/13187351/1/avalanchefailscommonsensetestkickedoutofgenetherapycredibilityclub.html. Zacks called the data "lackluster" and "weak" explaining that "results disappointed investors[.]" *Avalanche Biotechnologies Slips on Weak AVA-101 Data*, Zacks Equity Research (June 16, 2015), http://www.zacks.com/stock/news/178460/avalanche-biotechnologies-slips-on-weak-ava101-data. An article published on investing website, the Motley Foo, explained that "[t]he problem is that the retinas of patients receiving AVA-101 thickened relative to those in the control group, casting doubt on the gene therapy's efficacy as a treatment for wet AMD[,]" "one would expect the *exact* opposite result if AVA-101 was truly helping patients maintain their visual acuity." George Budwell, *Why Avalanche Biotechnologies, Inc. Stock Collapsed Today*, Motley Fool (June 16, 2015), http://www.fool.com/investing/general/2015/06/16/why-avalanche-biotechnologies-inc-stock-collapsed.aspx.

251. Accordingly, on this news shares of Avalanche common stock dropped $21.83, or more than 56%, to close on June 16, 2015 at $17.05 per share.

XVI. CLAIMS FOR RELIEF UNDER THE SECURITIES ACT

COUNT III

For Violations of Section 11 of the Securities Act Against The Securities Act Defendants

252. Plaintiff repeats and realleges each Securities Act allegation above as if fully set forth herein. This Count does not sound in fraud. Any allegations of fraud or fraudulent conduct and/or motive are specifically excluded. For purposes of asserting this and other claims under the Securities Act, Plaintiff does not allege that the Securities Act Defendants acted with intentional, reckless or otherwise fraudulent intent.

253. This Count is asserted against the Securities Act Defendants for violations of Section 11 of the Securities Act (15 U.S.C. § 77k), on behalf of all Class members who purchased the

Avalanche common stock sold in or traceable to the Avalanche IPO. The 2014 Registration Statement contained misrepresentations of material facts and omitted to state material facts required to be stated in order to make the statements contained therein not misleading.

254. As the issuer of the registered securities, Avalanche is strictly liable for the misleading statements and omission of material described herein.

255. None of the other Securities Act Defendants made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the 2014 Registration Statement were true or that there was no omission of material facts necessary to make the statements made therein not misleading.

256. The Securities Act Defendants, issued, caused to be issued, and participated in the issuance of materially false and misleading statements to the investing public that were contained in the 2014 Registration statement, and that misrepresented and/or failed to disclose, inter alia, the facts set forth above. As a direct and proximate result of the Securities Act Defendants' wrongful conduct, the market price for Avalanche common stock was artificially inflated in the 2014 Offering, and Plaintiff and the Class suffered substantial damages in connection with the purchase of Avalanche common stock during the Class Period.

257. In connection with offering the registered common stock to the public and the sale of those securities, the Securities Act Defendants named in this Count, directly or indirectly, used the means and instrumentalities of interstate commerce, the United States mails, and a national securities exchange.

258. This action was brought within one year after the discovery of the untruthfulness of the statements and omissions or after such discovery should have been made by the exercise of reasonable diligence and within three years after Avalanche common stock was offered to the public.

259. Class members did not know, nor in the exercise of reasonable diligence could they have known, that the 2014 Registration Statement contained untrue statements of material fact and

omitted to state material facts required to be stated or necessary to make the statements particularized above not misleading when they purchased the registered securities.

260. As a result of the foregoing, the defendants named in this Count are liable for violations of Section 11 of the Securities Act to Plaintiff and the other Class members who purchased the stock sold in or traceable to the Avalanche IPO.

COUNT IV

For Violations of Section 15 of the Securities Act Against the Individual Securities Act Defendants

261. Plaintiff repeats and realleges each Securities Act allegation above as if fully set forth herein. This Count does not sound in fraud. Any allegations of fraud or fraudulent conduct and/or motive are specifically excluded. For purposes of asserting this and other claims under the Securities Act, Plaintiff does not allege that the Securities Act Defendants acted with intentional, reckless or otherwise fraudulent intent.

262. This Count is alleged against the Individual Securities Act Defendants for violations of Section 15 of the Securities Act (15 U.S.C. § 77o), on behalf of Plaintiff and the other Class members who purchased Avalanche common stock sold in or traceable to the Avalanche IPO.

263. As set forth in Count III herein, Avalanche is liable pursuant to Section 11 of the Securities Act. At all relevant times, the Individual Securities Act Defendants were controlling persons of Avalanche within the meaning of Section 15 of the Securities Act. The Individual Securities Act Defendants served as executive officers and/or directors of Avalanche prior to and at the time of the IPO as alleged herein.

264. Each of the Individual Securities Act Defendants was a culpable participant in the violations of Section 11 of the Securities Act alleged in Count III above, based on their having signed the 2014 Registration Statement and having otherwise participated in the process that allowed the 2014 Offering to be executed. The Individual Securities Act Defendants, by virtue of their managerial and/or board positions with the Company, controlled the Company, as well as the content of the 2014 Registration Statement, at the time of the 2014 Offering. Each of the Individual

Securities Act Defendants was provided with or had unlimited access to the 2014 Registration Statement, and had the ability to prevent its issuance or cause it to be corrected.

265. As a direct and proximate result of the Individual Securities Act Defendants' wrongful conduct, the market price for Avalanche common stock was artificially inflated in the 2014 Offering, and Plaintiff and the Class suffered substantial damages in connection with the purchase of Avalanche common stock during the Class Period.

266. This action was brought within one year after the discovery of the untruthfulness of the statements and omissions or after such discovery should have been made by the exercise of reasonable diligence and within three years after Avalanche common stock was offered to the public.

267. As a result of the aforementioned, the Individual Securities Act Defendants are liable under Section 15 of the Securities Act, to the same extent that Avalanche is liable under Section 11 of the Securities Act, to Plaintiff and the other Class members who purchased securities pursuant or traceable to the Avalanche IPO.

CLASS ACTION ALLEGATIONS

268. Plaintiffs bring this action pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of themselves and all persons and entities who (1) purchased Avalanche common stock between July 31, 2014 and June 15, 2015, inclusive, and were damaged thereby, seeking to pursue remedies under the Exchange Act, and/or (2) purchased Avalanche common stock pursuant or traceable to the Avalanche IPO, defined herein, and were damaged thereby, seeking to pursue remedies under the Securities Act.

269. Excluded from the Class are the Defendants named herein, members of their immediate families, any firm, trust, partnership, corporation, officer, director or other individual or entity in which a Defendant has a controlling interest or which is related to or affiliated with any of the Defendants, and the legal representatives, heirs, successors-in-interest or assigns of such excluded persons.

270. The members of the Class are so numerous that joinder of all members is impracticable. During the Class Period, Avalanche common stock was actively traded on the NASDAQ GM, which is an efficient market. While the exact number of Class members cannot be determined at this early stage, Plaintiff believes that thousands of people held Avalanche common stock during the Class Period. Record owners and other members of the Class may be identified from records maintained by Avalanche or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

271. Plaintiffs' claims are typical of the claims of the other members of the Class. All members of the Class were similarly affected by Defendants' allegedly wrongful conduct in violation of the Exchange Act and Securities Act as complained of herein.

272. Plaintiffs will fairly and adequately protect the interests of the Class and have retained counsel competent and experienced in class action and securities litigation. Plaintiffs have no interests that are contrary to or in conflict with those of the Class.

273. Common questions of law and fact exist as to all members of the Class, and predominate over any questions solely affecting individual members of the Class. The questions of law and fact common to the Class include, *inter alia*:

a) Whether the federal securities laws were violated by Defendants' acts as alleged herein;

b) Whether statements made by Defendants during the Class Period contained untrue statements of material fact and/or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

c) Whether and to what extent Defendants' material untrue statements and/or omissions of material fact caused the market price of Avalanche's common stock to be artificially inflated during the Class Period;

d) Whether Defendants acted with the requisite level of scienter with respect to the Exchange Act claims;

e) Whether the Individual Exchange Act Defendants and Individual Securities Act Defendants were controlling persons of Avalanche;

f) Whether reliance may be presumed pursuant to the *Affiliated Ute* presumption, fraud-on-the-regulatory process, or fraud-on-the-market doctrine for the Exchange Act Claims; and

g) Whether the Class members have sustained damages, and if so, the proper measure of damages.

274. Plaintiffs know of no difficulty that will be encountered in the management of this action that would preclude its maintenance as a class action.

275. A class action is superior to all other available methods for the fair and efficient adjudication of this action because, among other things, joinder of all members of the Class is impracticable. In addition, since the damages suffered by individual members of the Class may be relatively small, the expense and burden of individual litigation would make it nearly impossible for members of the Class to bring individual actions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs on behalf of themselves and the Class, pray for relief and judgment including:

A. Determining that Counts I through IV of this action are a proper class action under Federal Rules of Civil Procedure 23, certifying Plaintiffs as Class representatives under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs' counsel as Class Counsel;

B. Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be determined at trial, including pre-judgment and post-judgment interest, as allowed by law;

C. Awarding rescissory damages in favor of Plaintiffs and the other Class members where appropriate against all Defendants, jointly and severally, for all injuries sustained as a result

of Defendants' wrongdoing, in an amount to be determined at trial, including pre-judgment and post-judgment interest, as allowed by law;

D. Awarding extraordinary, equitable, and/or injunctive relief as permitted by law (including, but not limited to, rescission);

E. Awarding Plaintiffs and the Class their costs and expenses incurred in this action, including reasonable counsel fees and expert fees; and

F. Awarding such other and further relief as may be just and proper.

JURY TRIAL DEMAND

Plaintiffs hereby demand a trial by jury on all triable claims.

Dated: January 29, 2016

FARUQI & FARUQI, LLP

By: */s/ Richard W. Gonnello*__

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CERTIFICATE OF SERVICE

I hereby certify that on January 29, 2016, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the attached Electronic Mail Notice List.

By: */s/ Richard W. Gonnello*
Richard W. Gonnello

Mailing Information for a Case No. 15-cv-03185-JD In re: Avalanche Biotechnologies Securities Litigation

Electronic Mail Notice List

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Mail Notice List

The following is a list of attorneys who are not on the list to receive e-mail notices for this case (who therefore require manual noticing). You may wish to use your mouse to select and copy this list into your word processing program in order to create notices or labels for these recipients.

- (No manual recipients)